

The diabetes technology landscape

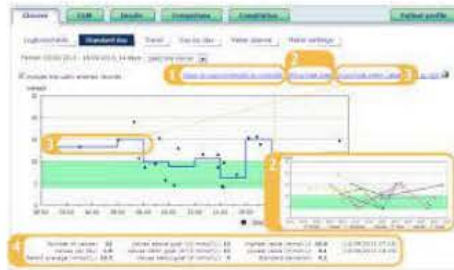
Glucose
sensing



Insulin
delivery



Data
management







Overview & Recent Advancements in Continues Glucose Monitoring Systems

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Gabric Diabetes Education Association

14th ICED

23 Nov 2023

Tehran, Iran

An abnormal hemoglobin in red cells of diabetics

In a survey carried out on 1200 patients from Tehran University Hospitals, in addition to three rare hemoglobins which are under investigation both in our department here and at the University of Cambridge, two patients also showed an abnormal fast moving hemoglobin fraction: both were suffering from diabetes mellitus.

Studies were started to investigate the occurrence of this abnormal fraction in other diabetics, and in 47 cases examined in the last three months, including 11 children with severe diabetes mellitus, the additional fraction was detected. Routine hematological examination according to standard methods⁶ gave normal results in the majority of cases.

Electrophoresis of hemoglobin was carried out on cellulose acetate according to Graham and Gruenbaum³; the abnormal fraction does not separate well by this method, but there is a broadening of the Hb A band. In starch gel electrophoresis with tris-EDTA-borate buffer pH 8.1 (ref. 1) the additional fraction moves a little faster than Hb A and slower than Hb J (Iran)⁴ (Fig. 1).

Agar gel electrophoresis in citrate buffer pH 6.2 by the method of Robinson *et al.*⁵ is the method of choice for the separation and demonstration of this fraction which moves in front of Hb A to the cathode in the same position as Hb F (Fig. 2).

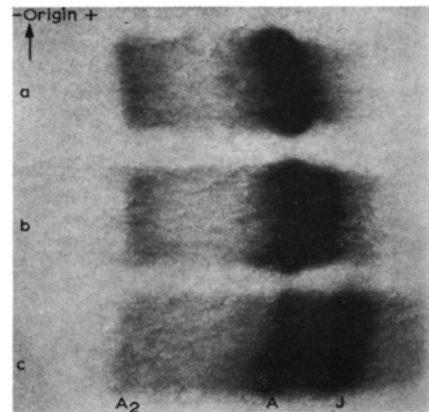
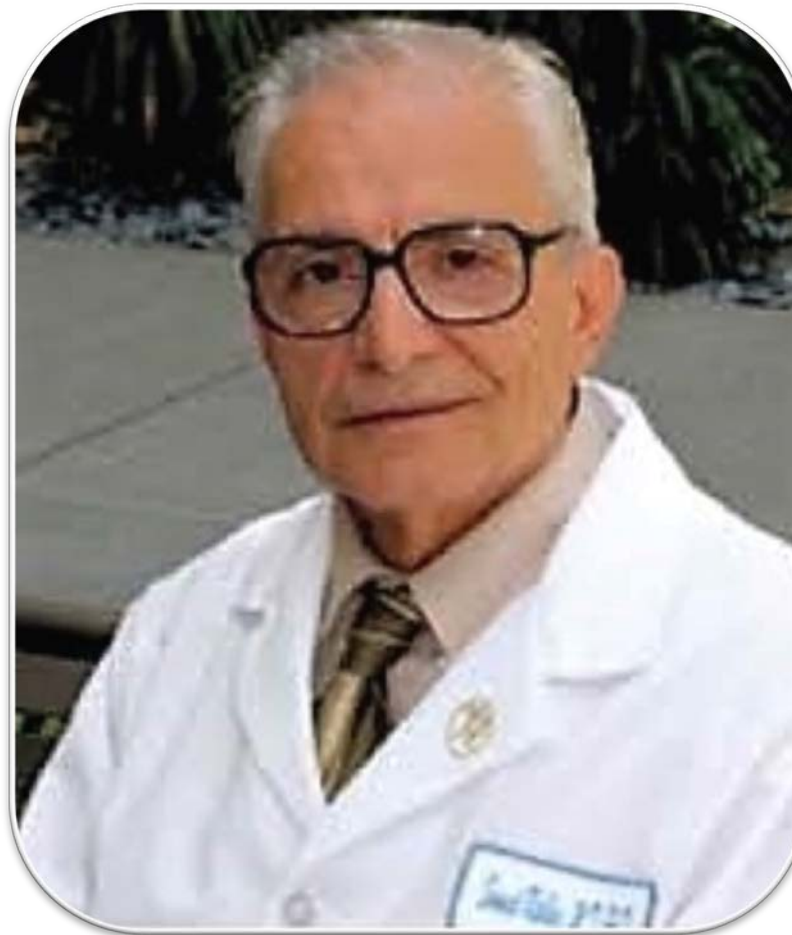


Fig. 1. Starch gel electrophoresis in tris-EDTA-borate buffer, pH 8.1. o-Dianizidine stain, ref. 7. a: normal; b: Hb A + Hb x; c: Hb A + Hb J (Iran).

Clin. Chim. Acta, 22 (1968) 296-298



History of Contemporary Medicine

Breakthrough Discovery of HbA_{1c} by Professor Samuel Rahbar in 1968

Mohammad Hossein Azizi MD¹, Moslem Bahadori MD², Farzaneh Azizi DVM³

Cite the article as: Azizi MH, Bahadori M, Azizi F. Breakthrough Discovery of HbA_{1c} by Professor Samuel Rahbar in 1968. *Arch Iran Med*. 2013; 16(12): 743-745.



Professor Samuel Rahbar

Professor Samuel Rahbar (May 12, 1929 – November 10, 2012) was an outstanding scholar who discovered the presence of an abnormally increased amount of glycated hemoglobin (HbA_{1c}) in the blood of patients with diabetes mellitus. This monumental discovery led to a significant improvement in the diagnosis and management of millions of diabetics all over the world.

From a biochemical point of view, an irreversible non-enzymatic glycation of the beta chain of hemoglobin A results in HbA_{1c} formation which is currently used as a major biological marker and indicator of long-term glycemic control in diabetic patients.¹ The first clinically useful test for HbA_{1c} content was introduced around 1977 to monitor the management of diabetes, although its accuracy was still poor. Then in 1991, the first commercial immunoassay test became available, and HbA_{1c} manual immunoassay analyzer has been in use since 1992.² Importantly, the test is now standardized and used world-over and, more recently, for the diagnosis of diabetes.³

Samuel Rahbar was born in Hamadan, Iran in 1929. He enrolled in the Tehran University Medical School and graduated in 1953. In due course, Dr. Rahbar practiced medicine in Abadan and Tehran till 1959. Thereafter, he started his postdoctoral immunology fellowship at Tehran University and received his PhD in 1963. He was promoted to Assistant Professor at the Department of Immunology and then became an Associate Professor in 1965.⁴

His influential paper and a genuine breakthrough entitled "Abnormal Hemoglobin in Red Cells of Diabetics" was published in an international journal of clinical chemistry and diagnostic laboratory medicine named *Clinica Chimica Acta* in October 1968. There he wrote: "In a survey carried out on 1200 patients from

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Accepted for publication: 18 November 2013

Tehran University Hospitals, in addition to three rare hemoglobins which are under investigation both in our department here and at the University of Cambridge, two patients also showed an abnormal fast moving hemoglobin fraction: both were suffering from diabetes mellitus." He also added that more studies were initiated to explore the occurrence of this abnormal fraction in other diabetics and HbA_{1c} was detected in 47 cases surveyed within the next three months, including two children with severe diabetes mellitus. In most cases, routine hematological examination according to standard methods yielded normal results (Figure 1).⁵ This paper has been cited 344 times.



Figure 1. Professor Rahbar's paper in *Clinica Chimica Acta*, Volume 22, Issue 2, October 1968, Pages 296-298 (Available from: [http://dx.doi.org/10.1016/0009-8981\(68\)90372-0](http://dx.doi.org/10.1016/0009-8981(68)90372-0) Accessed 4.8.2013.)

Between 1968 and 1969, Professor Rahbar was a visiting professor at the Department of Medicine at the "Albert Einstein College of Medicine" in New York and he collaborated with Professor Helen M. Ramsey (1.2010), a pioneering scholar who significantly contributed to the study of sickle cell anemia in children.^{6,7} Upon return to Tehran, Professor Rahbar became full professor in 1970 and was assigned as Director of the Department of Applied Biology at the Medical School of University of Tehran. In addition to HbA_{1c} discovery, Dr. Rahbar examined 220,000 blood samples over a period of 15 years from different hospitals in Tehran and eventually detected 11 new variants of hemoglobin in Iran (Figure 2). For nomenclature of these new hemoglobins, Professor Rahbar used Persian words in his papers such as Iran,

Archives of Iranian Medicine, Volume 16, Number 12, December 2013 743

Table 1—HbA_{1c}: a history

1966: Holmquist and Schroeder identify five subtypes of hemoglobin A, including HbA _{1c} .
1968: Rahbar recognizes that HbA _{1c} is elevated in people with diabetes.
1975: Koenig and Cerami suggest that HbA _{1c} is related to metabolic control.
1993: DCCT establishes HbA _{1c} as a valuable clinical marker in people with type 1 diabetes.
1998: UKPDS establishes HbA _{1c} as a valuable clinical marker in people with type 2 diabetes.
2010: ADA recommends using the HbA _{1c} test to diagnose diabetes and prediabetes.

The Start of Something Good: The Discovery of HbA_{1c} and the American Diabetes Association Samuel Rahbar Outstanding Discovery Award

Sometimes, a scientific achievement merits its own prize. The American Diabetes Association (ADA) acknowledged Samuel Rahbar, MD, PhD, with just such an honor—the Samuel Rahbar Outstanding Discovery Award—for a contribution to the study and treat-

ment, Rahbar returned to Iran to establish such a research program. Rahbar hoped to find novel hemoglobin variants hidden in the blood of his compatriots.

mentor, Rahbar returned to Iran to establish such a research program. Rahbar hoped to find novel hemoglobin variants hidden in the blood of his compatriots.

Gearing up—The tool of choice for analyzing hemoglobin variants at the time

Rahbar S. An abnormal hemoglobin in red cells of diabetics. *Clin Chim Acta*. 1968; 22:296-8.

Gebel E. *Diabetes Care*. 2012; 35:2429-31.

Azizi MH, et al. *Arch Iran Med*. 2013; 16:743 – 45.

25 years later: the DCCT established the importance of HbA_{1c}

The New England
Journal of Medicine

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Volume 329 SEPTEMBER 30, 1993 Number 14

THE EFFECT OF INTENSIVE TREATMENT OF DIABETES ON THE DEVELOPMENT AND PROGRESSION OF LONG-TERM COMPLICATIONS IN INSULIN-DEPENDENT DIABETES MELLITUS

THE DIABETES CONTROL AND COMPLICATIONS TRIAL RESEARCH GROUP*

Abstract Background. Long-term microvascular and neurologic complications cause major morbidity and mortality in patients with insulin-dependent diabetes mellitus (IDDM). We examined whether intensive treatment with the goal of maintaining blood glucose concentrations close to the normal range could decrease the frequency and severity of these complications.

Methods. A total of 1441 patients with IDDM — 726 with no retinopathy at base line (the primary-prevention cohort) and 715 with mild retinopathy (the secondary-intervention cohort) were randomly assigned to intensive therapy administered either with an external insulin pump or by three or more daily insulin injections and guided by frequent blood glucose monitoring or to conventional therapy with one or two daily insulin injections. The patients were followed for a mean of 6.5 years, and the appearance and progression of retinopathy and other complications were assessed regularly.

Results. In the primary-prevention cohort, intensive therapy reduced the adjusted mean risk for the development of retinopathy by 76 percent (95 percent confidence interval, 62 to 85 percent), as compared with conventional therapy. In the secondary-intervention cohort, intensive therapy slowed the progression of retinopathy by 54 percent (95 percent confidence interval, 39 to 66 percent) and reduced the development of proliferative or severe nonproliferative retinopathy by 47 percent (95 percent confidence interval, 14 to 67 percent). In the two cohorts combined, intensive therapy reduced the occurrence of microalbuminuria (urinary albumin excretion of ≥ 40 mg per 24 hours) by 39 percent (95 percent confidence interval, 21 to 52 percent), that of albuminuria (urinary albumin excretion of ≥ 300 mg per 24 hours) by 54 percent (95 percent confidence interval, 19 to 74 percent), and that of clinical neuropathy by 60 percent (95 percent confidence interval, 38 to 74 percent). The chief adverse event associated with intensive therapy was a two-to-threefold increase in severe hypoglycemia.

Conclusions. Intensive therapy effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with IDDM. (N Engl J Med 1993;329:977-86.)

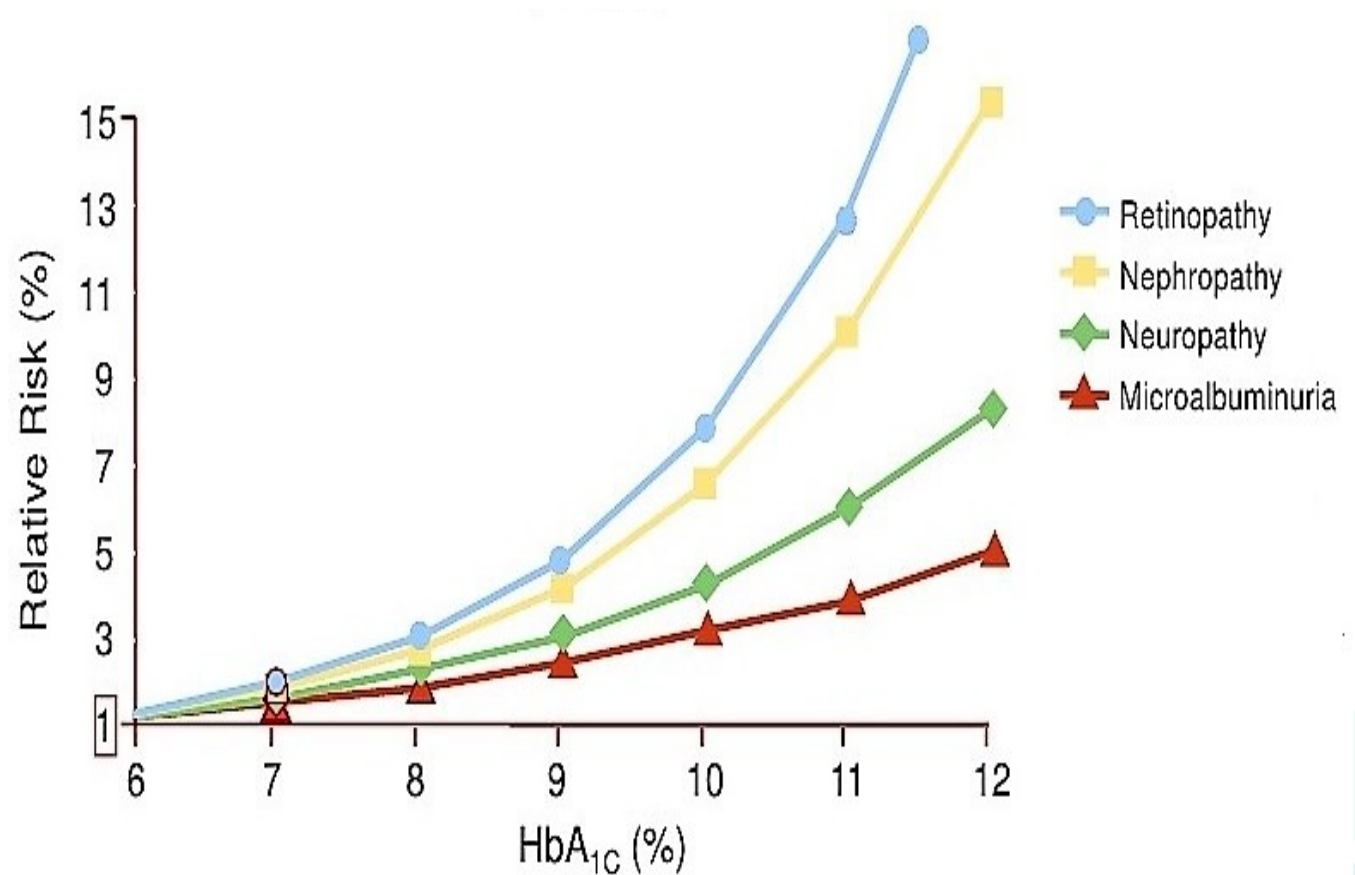
INSULIN-dependent diabetes mellitus (IDDM) is accompanied by long-term microvascular, neurologic, and macrovascular complications. Although the daily management of IDDM is burdensome and the specter of metabolic decompensation ever-present, long-term complications, including retinopathy, nephropathy, neuropathy, and cardiovascular disease, have caused the most morbidity and mortality since the introduction of insulin therapy.^{1,2} The prevention and amelioration of these complications have been major goals of recent research.

Although studies in animal models of diabetes³⁻⁵ and epidemiologic studies⁶⁻⁸ implicate hyperglycemia in the pathogenesis of long-term complications, previous clinical trials have not demonstrated a consistent or convincing beneficial effect of intensive therapy on them.⁹⁻¹¹ A recent publication from the Stockholm Diabetes Intervention Study demonstrated a more uniform beneficial effect of intensive therapy in patients with established complications, despite the apparent crossover of most conventionally treated patients to intensive therapy during the trial.¹²

The Diabetes Control and Complications Trial was a multicenter, randomized clinical trial designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications of IDDM.¹³⁻¹⁵ The intensive-therapy regimen was designed to achieve blood glucose values as close to the normal range as possible with three or more daily insulin injections or treatment with an insulin pump. Conventional therapy consisted of one or two insulin injections per day. Two cohorts of patients were studied in order to answer two different, but related, questions: Will intensive therapy prevent the development of diabetic retinopathy in patients with no retinopathy (primary prevention), and will intensive

*A complete list of the persons and institutions participating in the Diabetes Control and Complications Trial Research Group appears in the Appendix.

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The limitation of HbA_{1c} officially stated in “the Standards of Care 2018”

Diabetes Care Volume 41, Supplement 1, January 2018

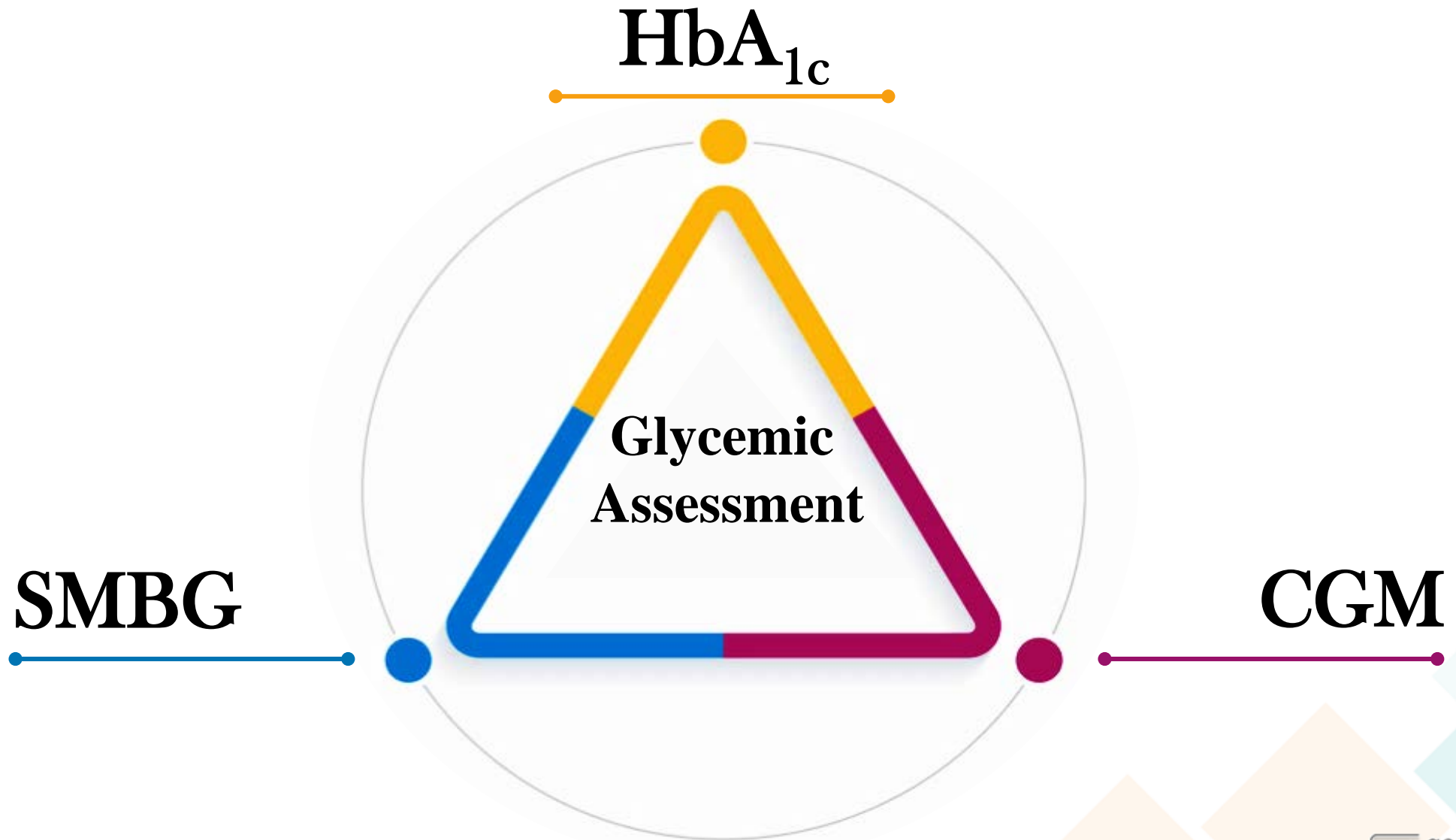
6. Glycemic Targets: *Standards of Medical Care in Diabetes—2018*

American Diabetes Association

Diabetes Care 2018;41(Suppl. 1):S55–S64 | <https://doi.org/10.2337/dc18-S006>

- *HbA_{1c} does not provide a measure of glycemic variability or hypoglycemia. For patients prone to glycemic variability, especially patients with T₁DM T₂DM with severe insulin deficiency, glycemic control is best evaluated by the combination of results from **HbA_{1c} and SMBG or CGM.***

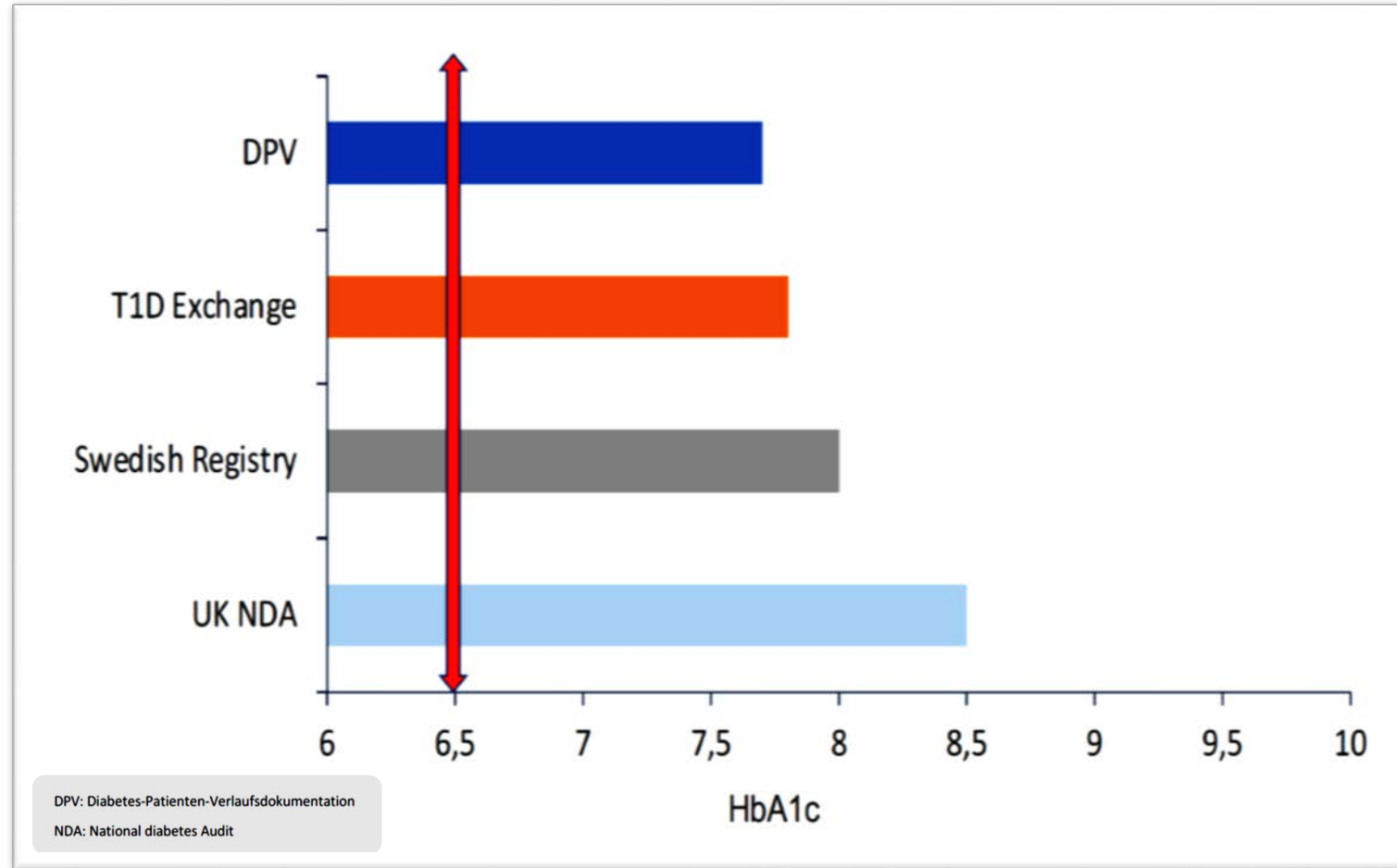
Glycemic Control Assessment



Really hard to achieve targets

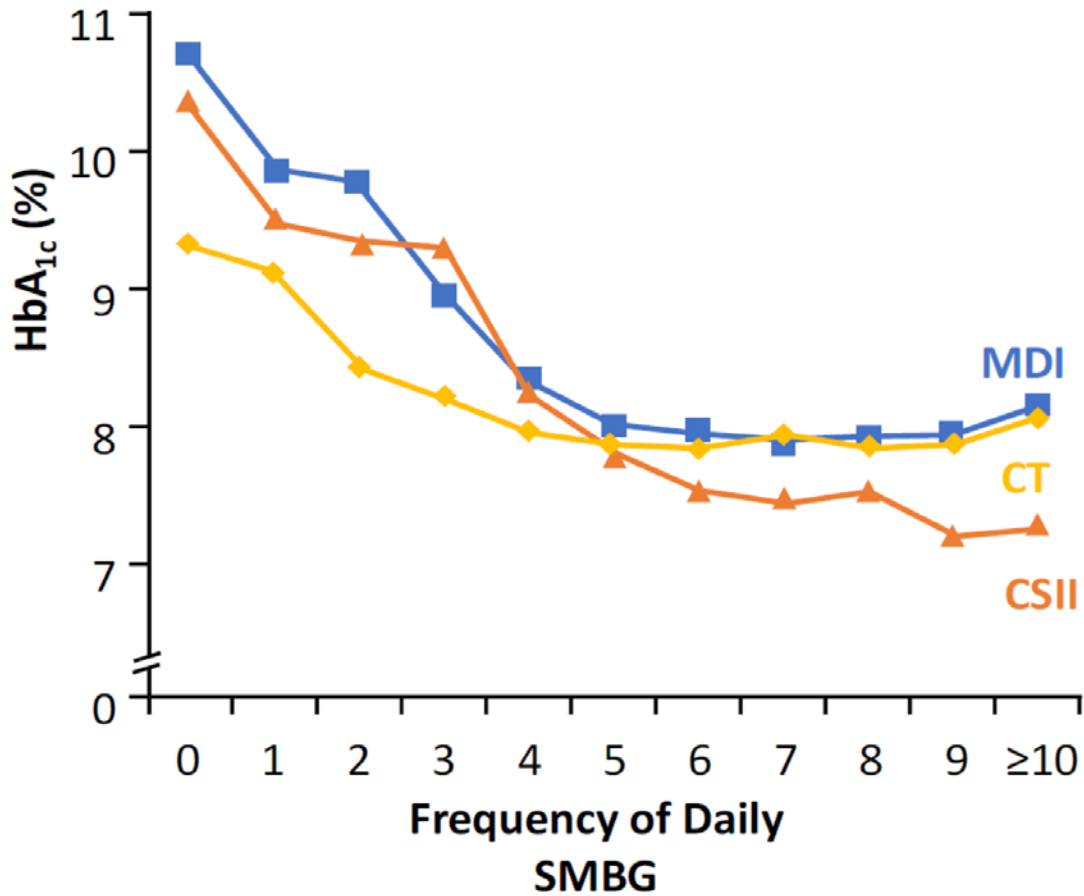
- 8-10 SMBG/day (*like CGM*)
- 6-8 injections/day (*like CSII*)
- Pre-attention to snacks, exercise
- Accurate carb counting
- Skills, motivation, perseverance, support, education... and **LUCK!**

○ **All the above, for everyday for the rest of your life!**

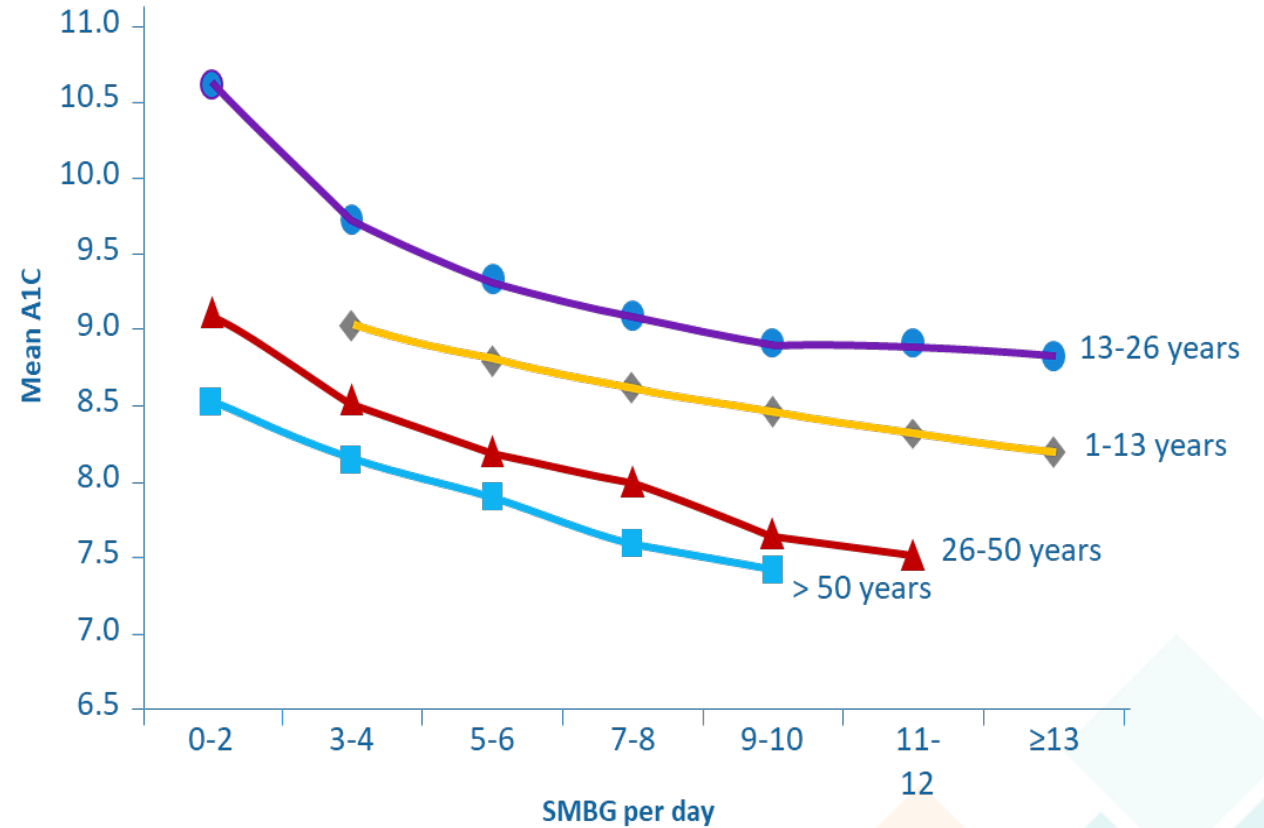


Ziegler, *Ped Diabetes*, 2011 Feb

T₁DM: correlation between greater SMBG frequency and lower HbA_{1c}

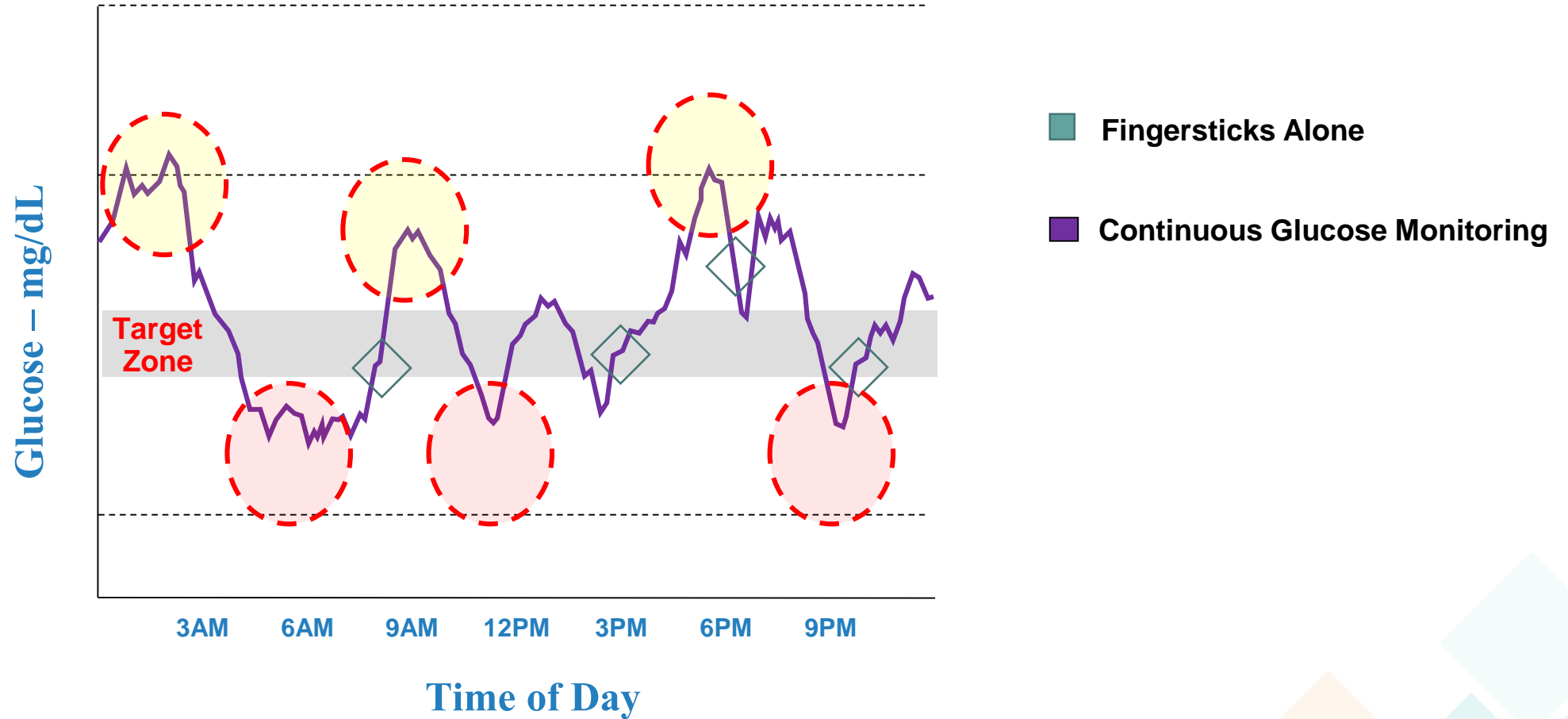


Ziegler R, et al. *Pediatr Diabetes*. 2011;12(1):11-7.



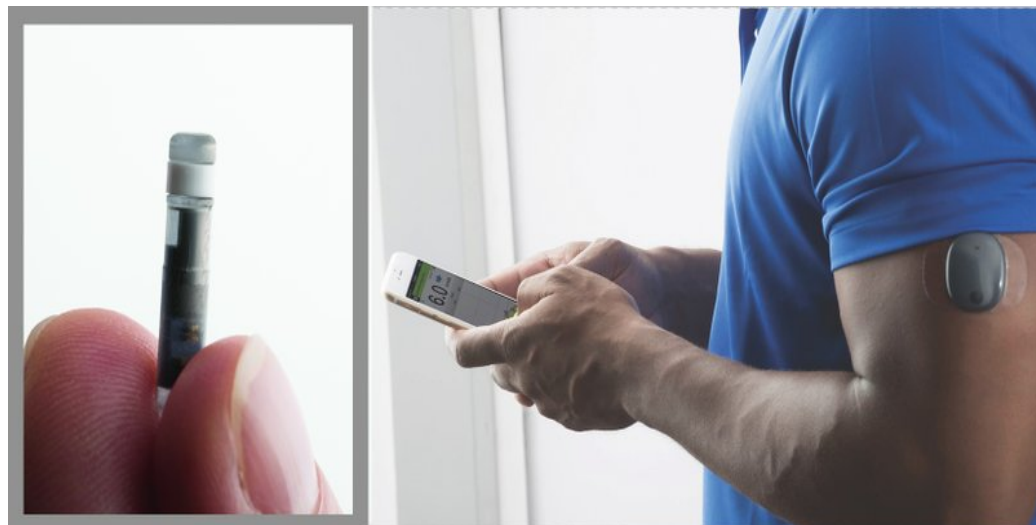
Miller KM, et al. *Diabetes Care*. 2013;36:2009-14..

CGM reveals insights beyond SMBG



New means of control

Continues Glucose Monitoring



Components of CGMs

A. Sensor



B. Transmitter



C. Receiver



Sensor + Transmitter

Receiver



Current availability and use of CGMSs

Key Players Within The CGM Industry



1999:
Medtronic MiniMed



2006:
Dexcom STS



2008:
Freestyle Navigator



Most popular CGMs

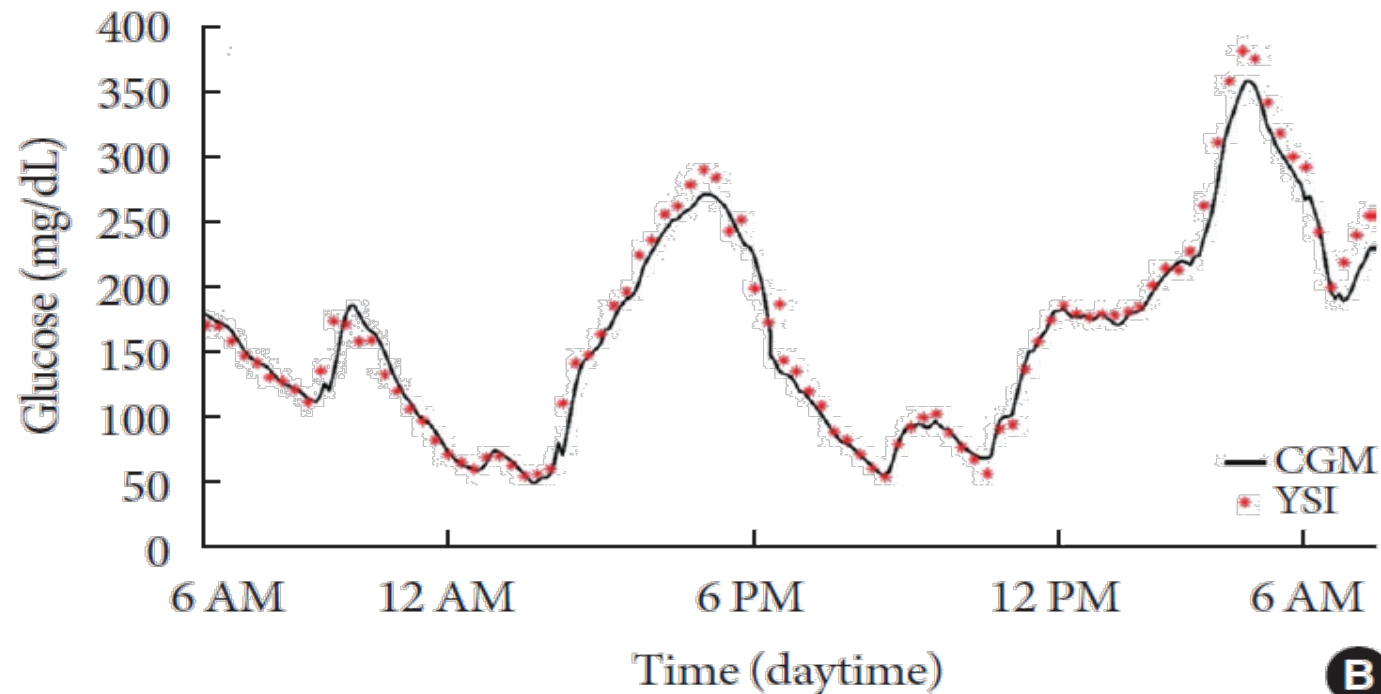


Dexcom

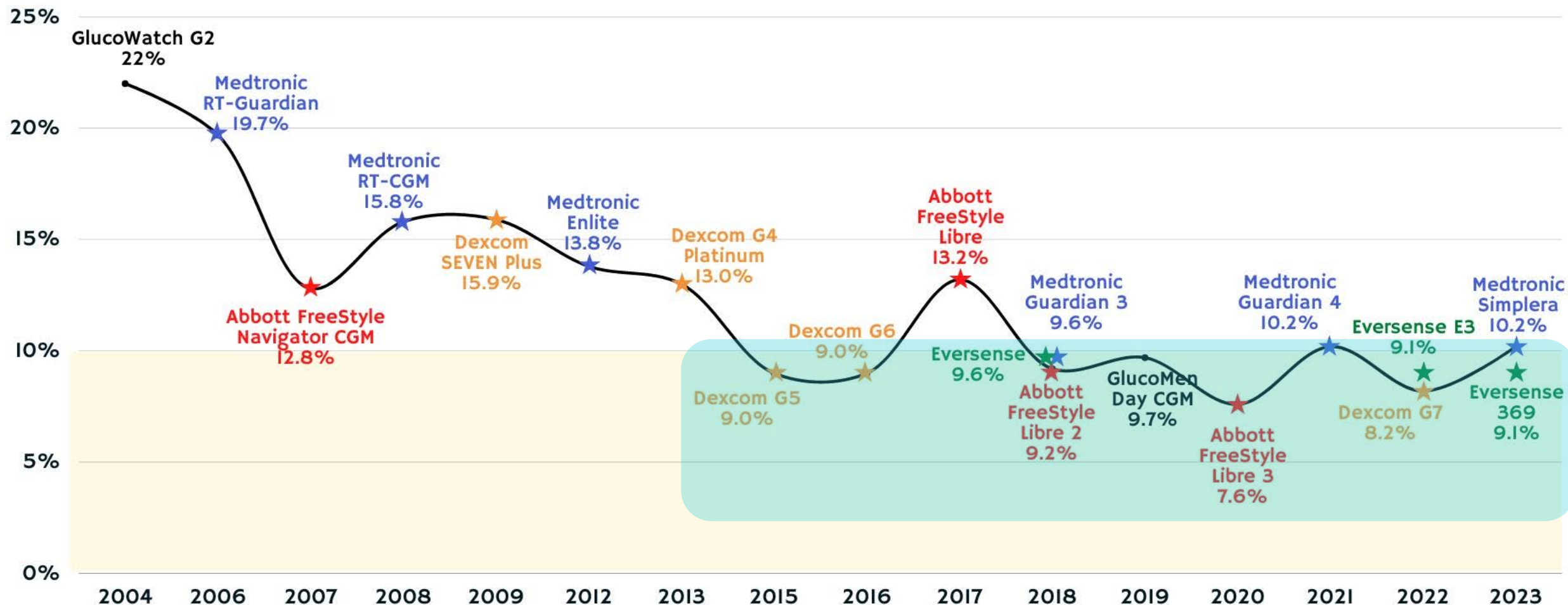
Accuracy

The mean absolute relative difference (**MARD**)

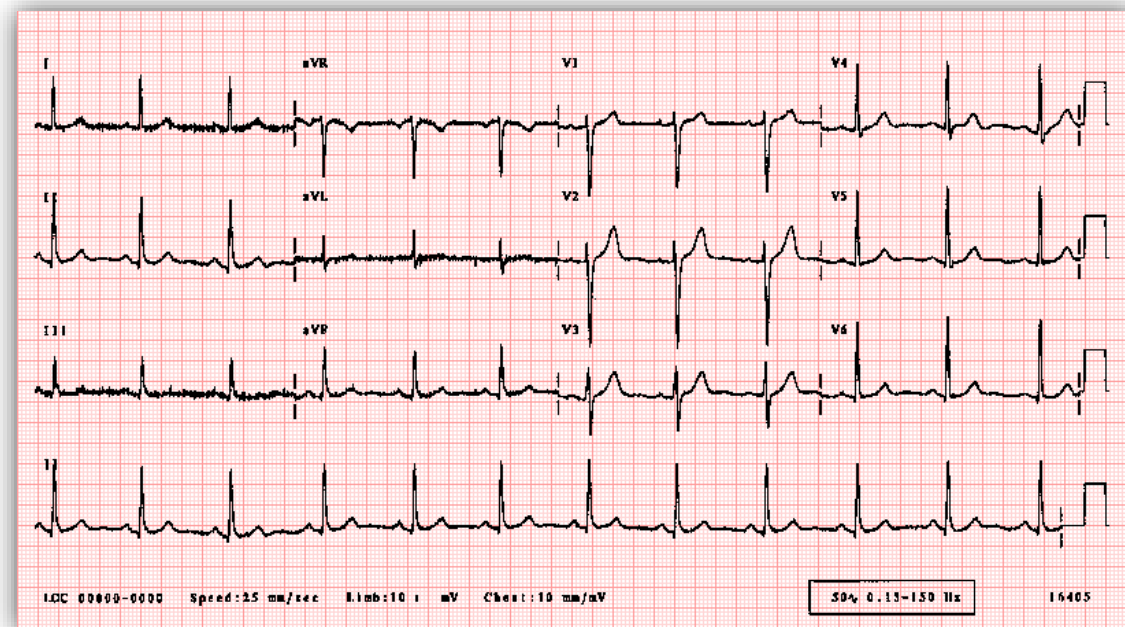
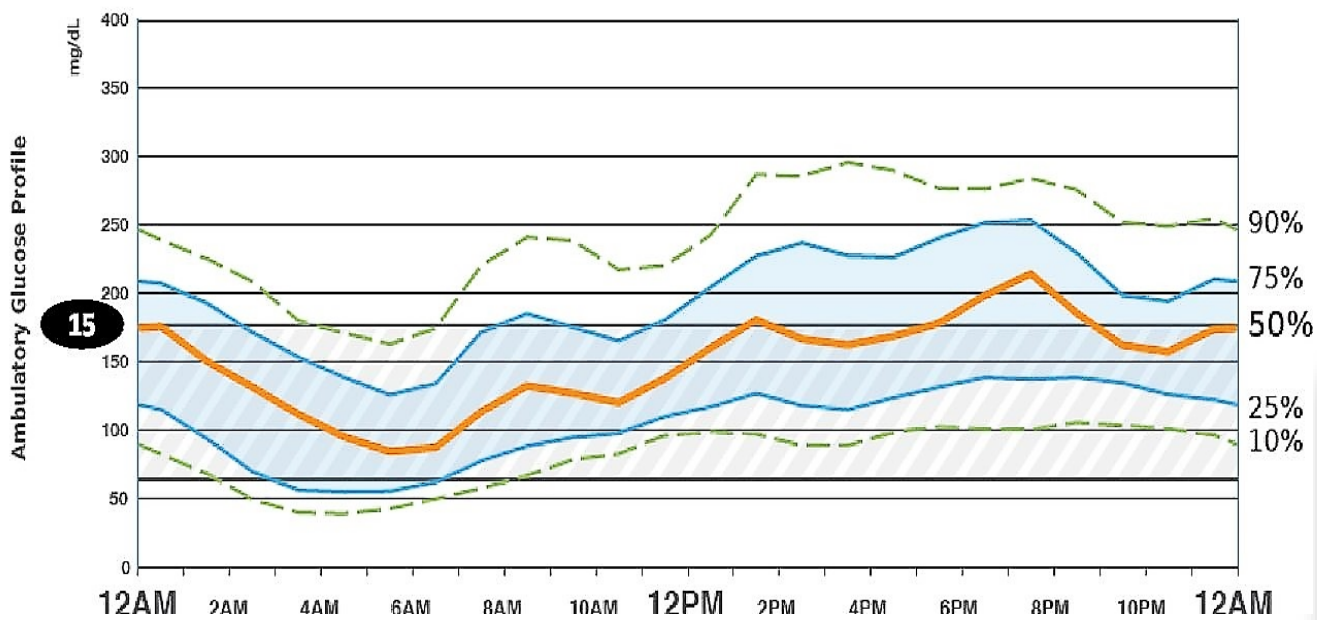
- Currently the most common metric used to assess the performance of CGM systems.
- MARD is the average of the absolute error between all CGM values and matched reference values.



Accuracy timeline of CGM devices

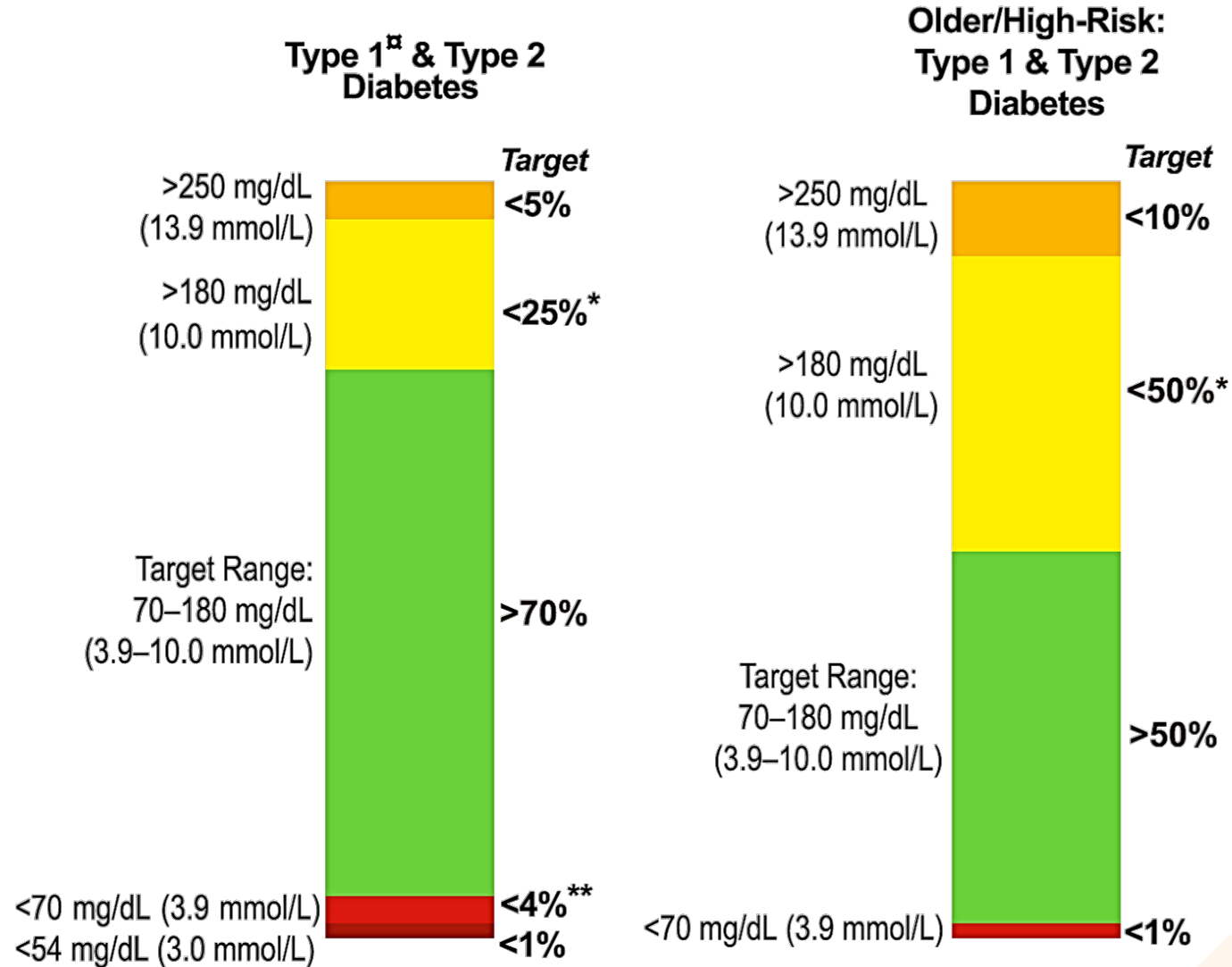


AGP*: The New ECG



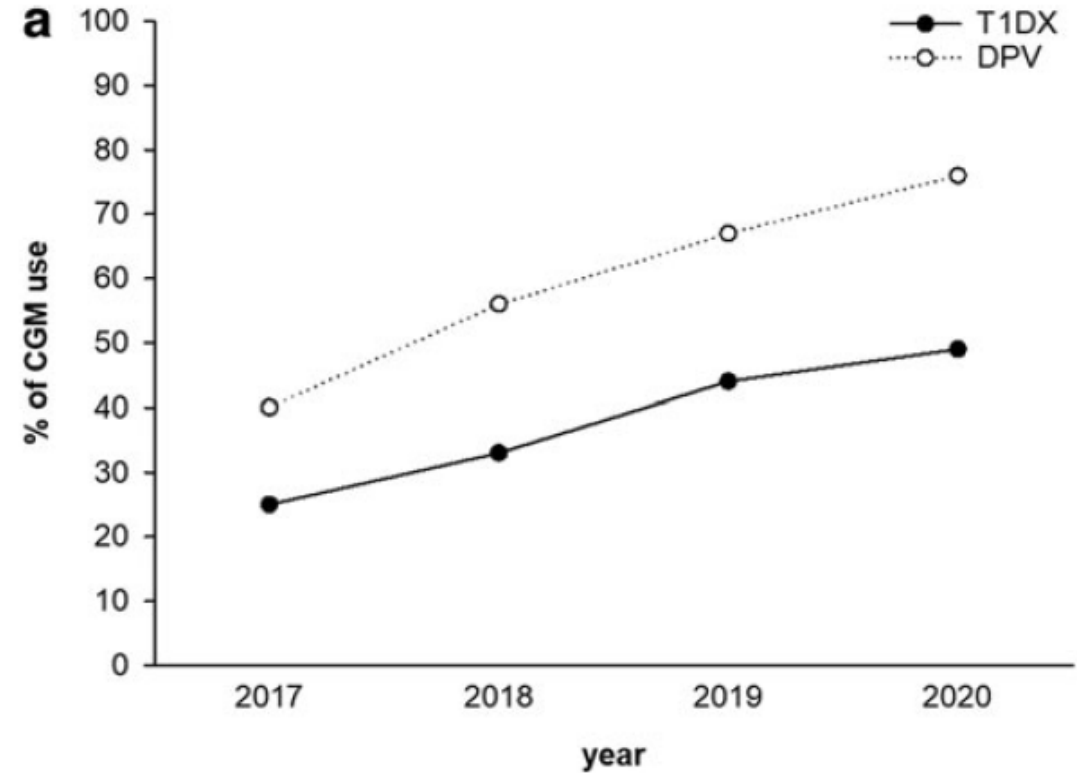
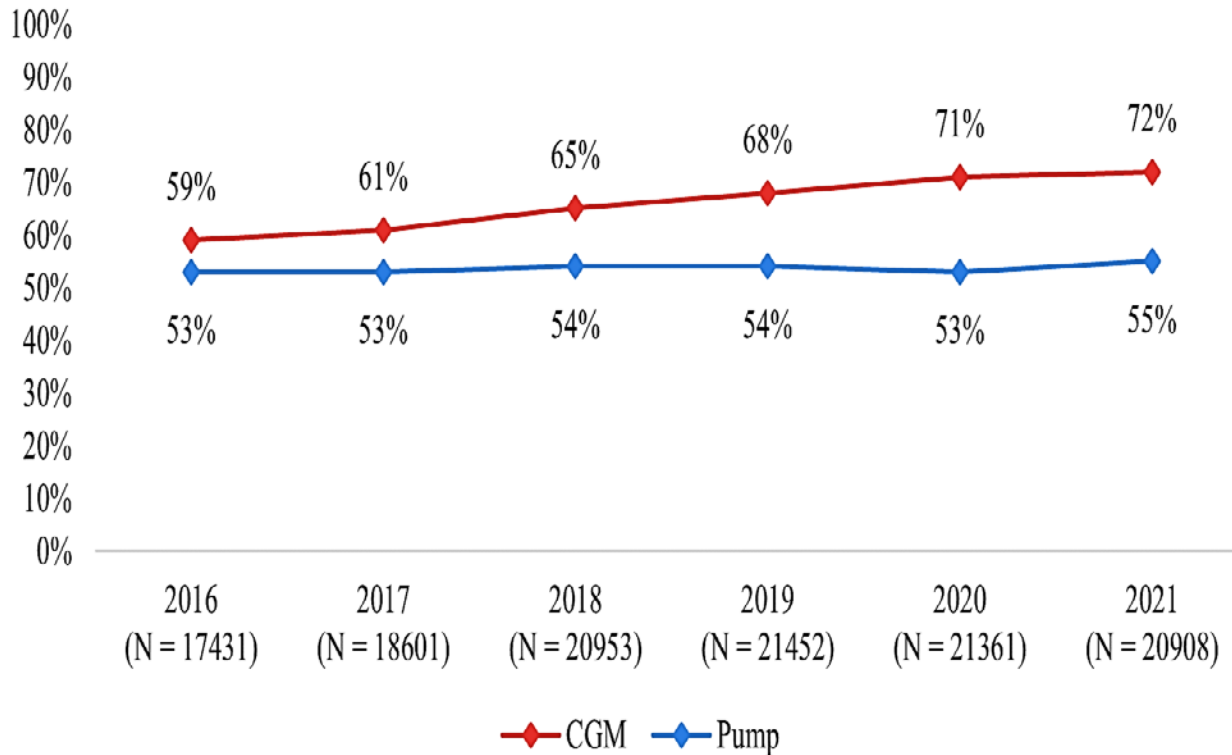
* Ambulatory Glucose Profile

CGM-based targets for different diabetes populations



Trend in CGM Use

American Diabetes Association From: **911-P: Longitudinal Trends in CGM and Pump Use: Real-World Data from the T1D Exchange QI Collaborative**

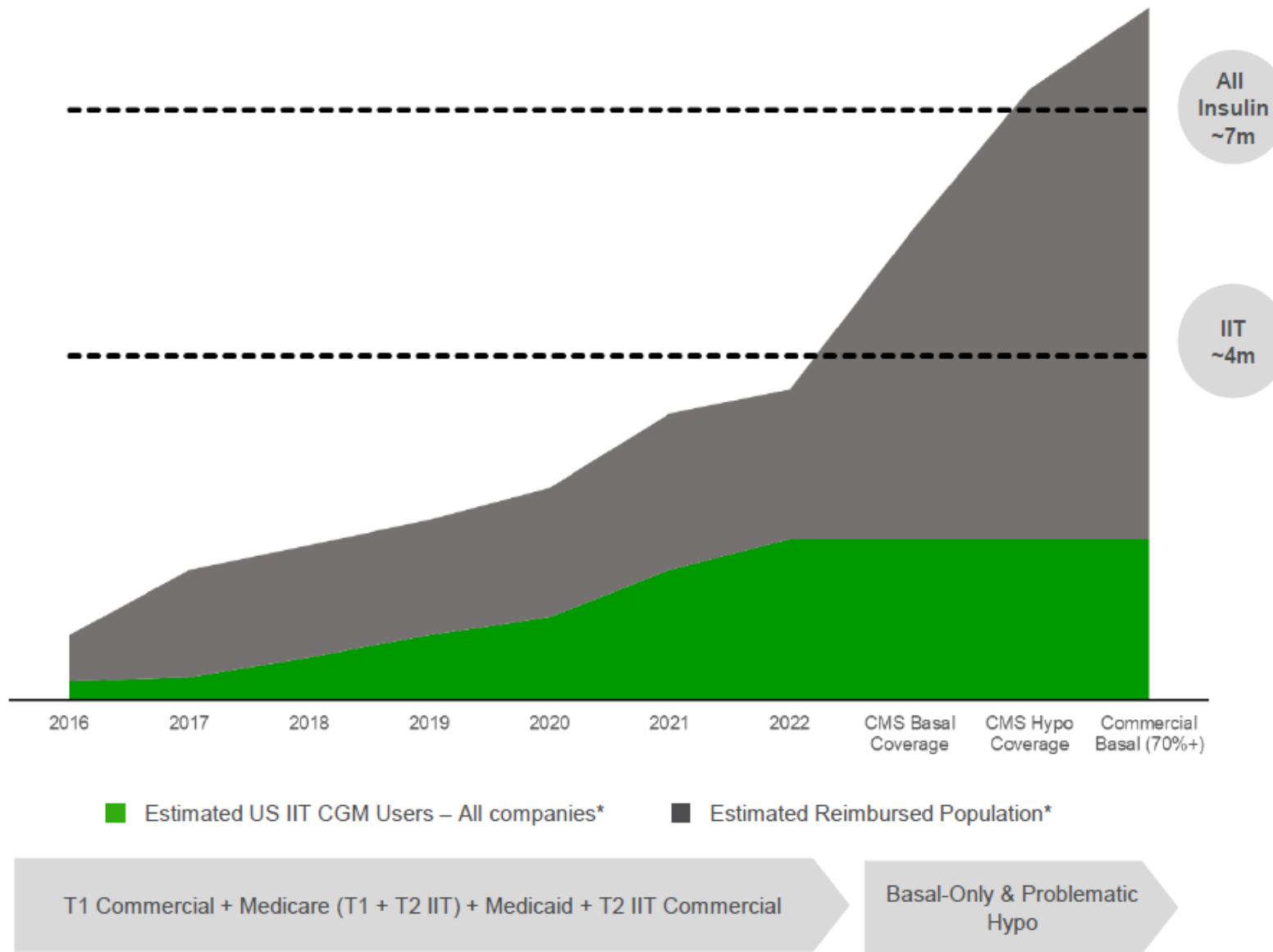


Core US Market

Momentum and opportunity remain significant

With coverage for basal insulin users and problematic hypoglycemia there is more people with access to CGM than ever before

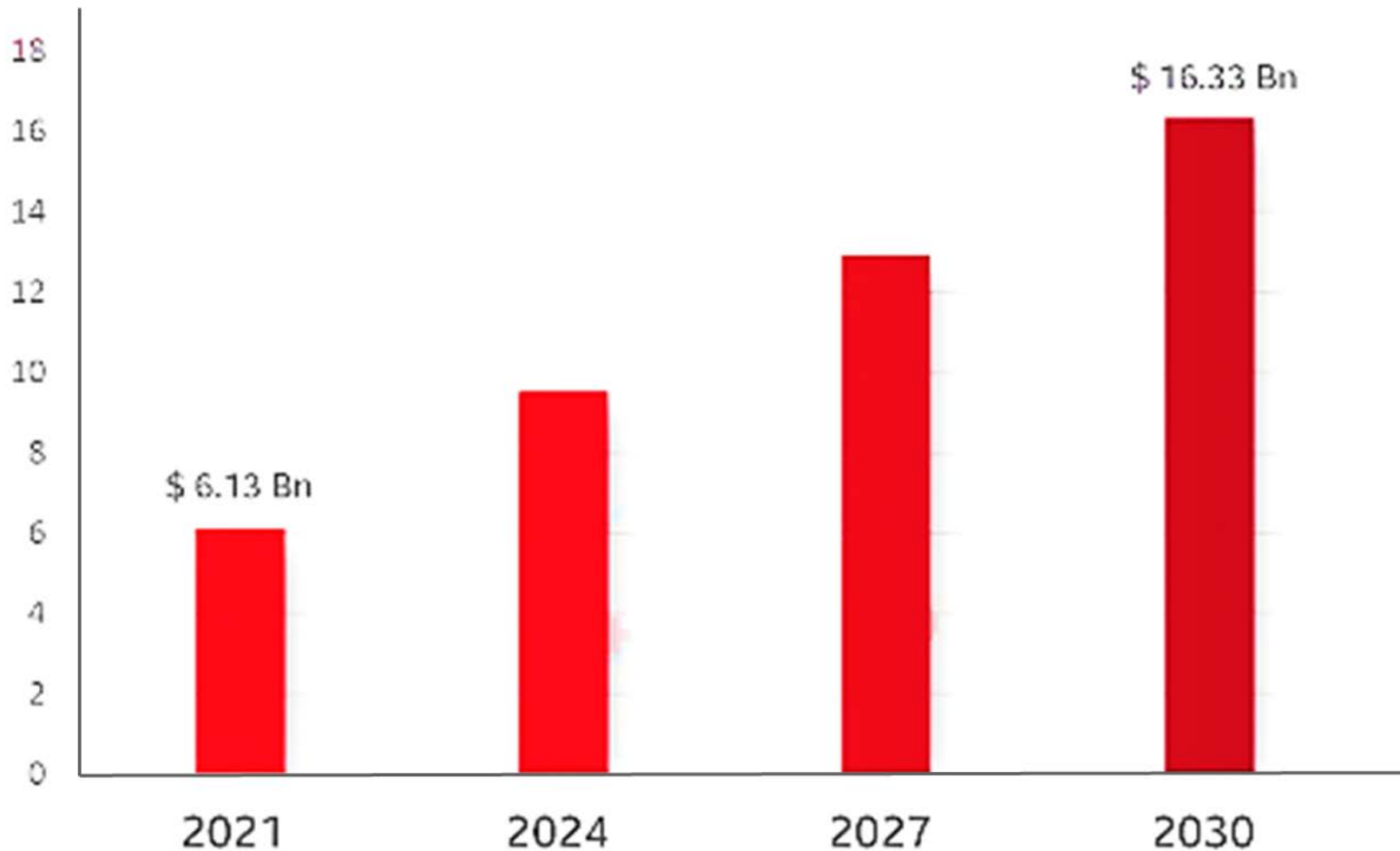
Insulin & Non-Insulin Hypoglycemia Population



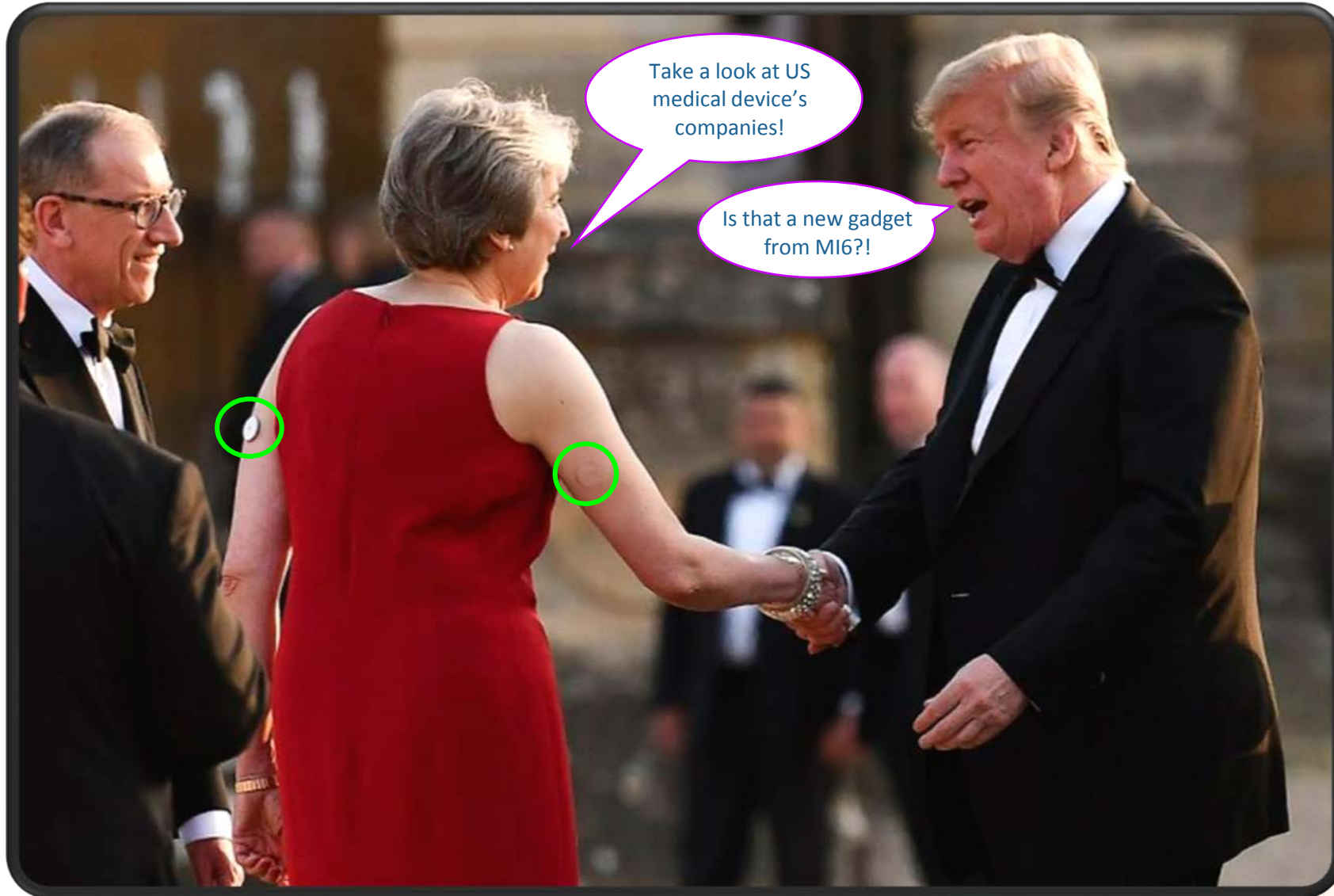
*Dexcom market research and Wall Street research. Estimated Reimbursed Population based on Dexcom market research.

Global CGM devices market research (2021-2030)

Most aggressive growth forecast of 11.5% (USD Billion)



Is Donald Trump still the hot topic?



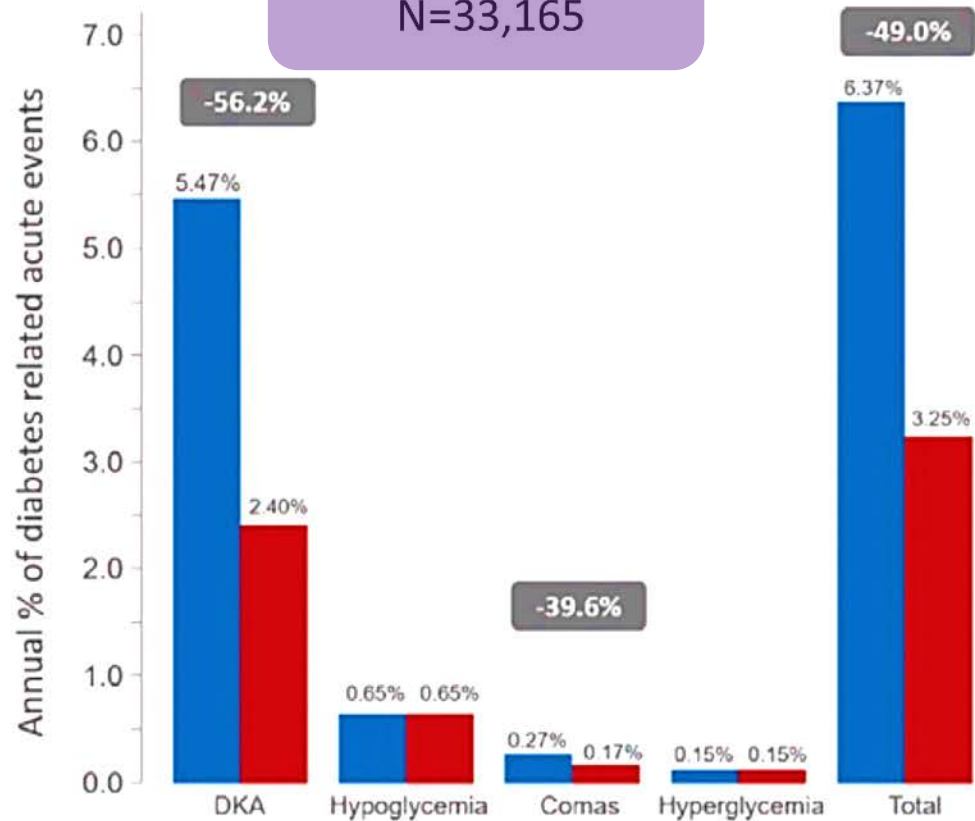
CGMS

Outcomes/efficacy

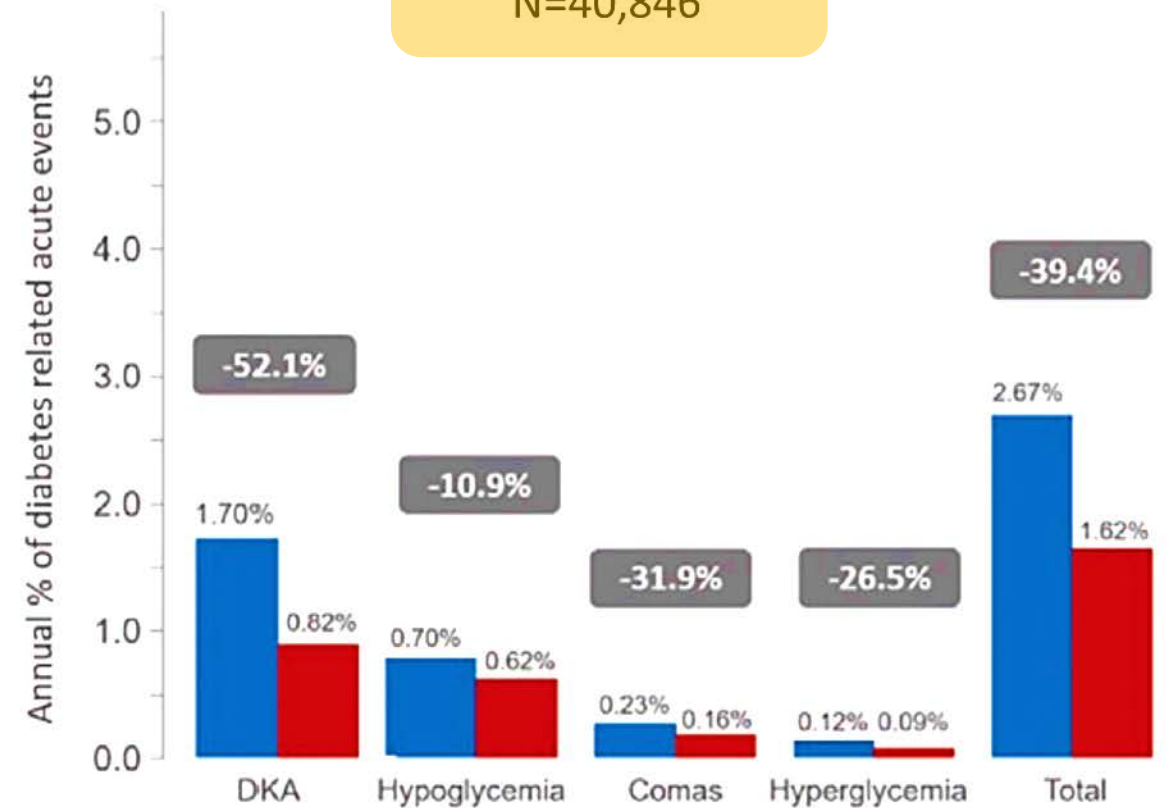
Recommendations

RELIEF study, MDI, France

A Type 1 diabetes
N=33,165

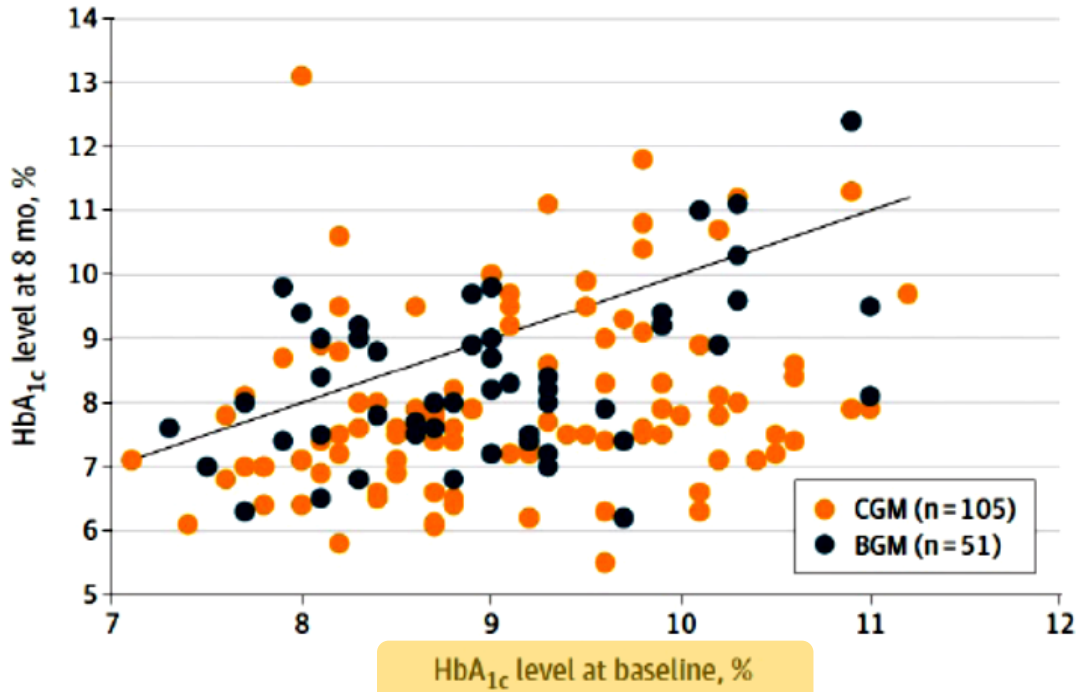


B Type 2 diabetes
N=40,846

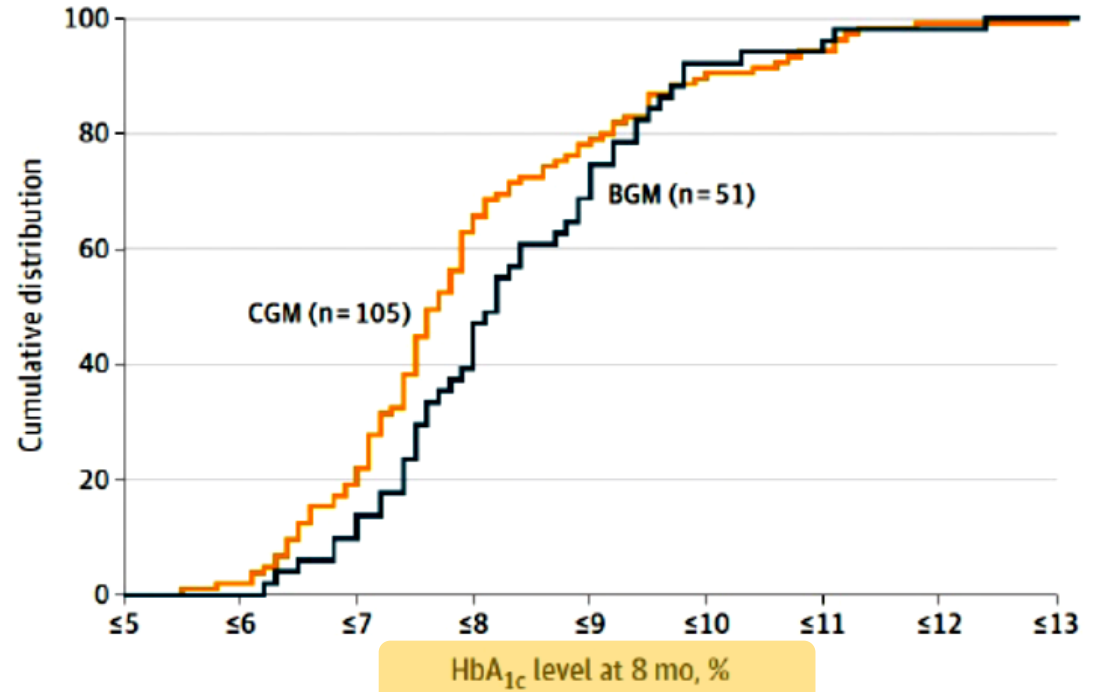


Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin A Randomized Clinical Trial

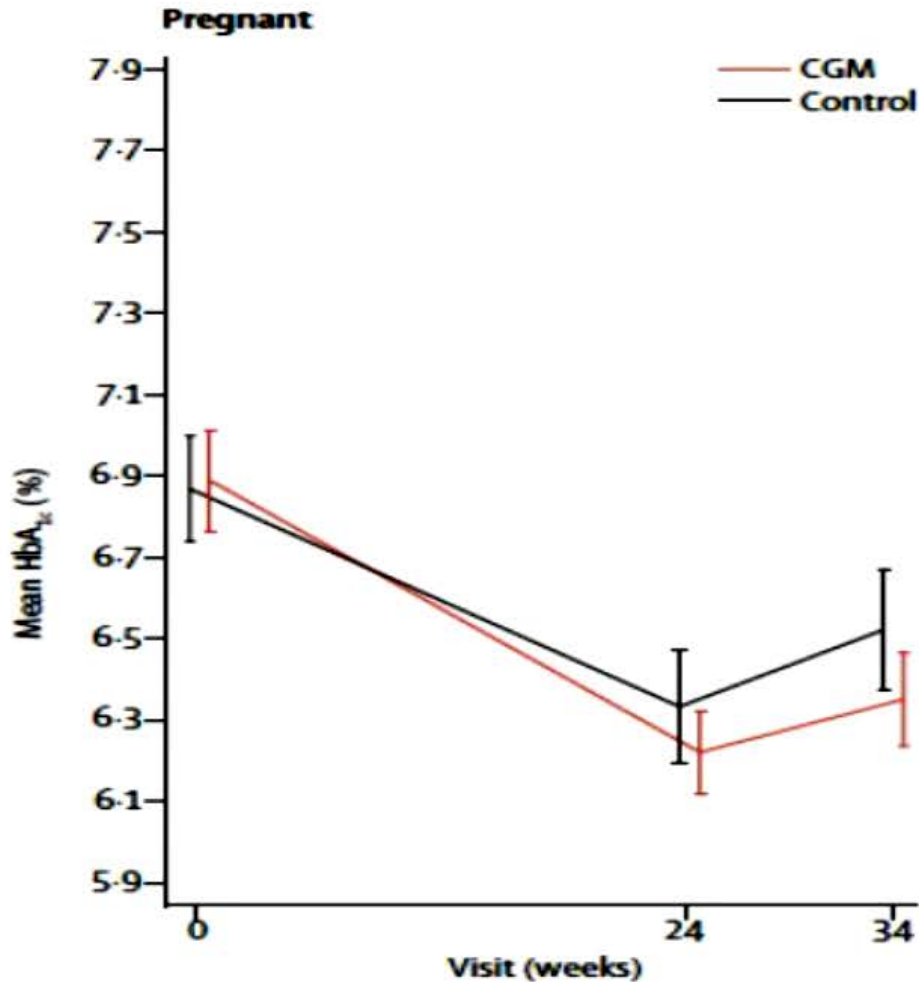
A 8-mo HbA_{1c} level by baseline HbA_{1c} level



B Cumulative distribution of 8-mo HbA_{1c} values



Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial



	CGM	Control
Stillbirth	0	1
Congenital Anomaly	2	3
Early preterm < 34 weeks	5%	7%
LGA > 90%	53%*	69%
Macrosomia > 4000g	23%*	27%
NICU > 24 hrs	27%*	43%

CGM Devices

7.11 rtCGM **A** or isCGM **B** should be offered for diabetes management in **adults with diabetes on MDI or CSII** who are capable of using the devices safely (either by themselves or with a caregiver).

7.12 rtCGM **A** or isCGM **C** should be offered for diabetes management in **adults with diabetes on basal insulin** who are capable of using the devices safely (either by themselves or with a caregiver).

7.13 rtCGM **B** or isCGM **E** should be offered for diabetes management in youth with **T₁D on MDI or CSII** who are capable of using the devices safely (either by themselves or with a caregiver).

Diabetes Technology:

Standards of Care in Diabetes - 2023. Diabetes Care 2023;46(Suppl. 1):S111-S127

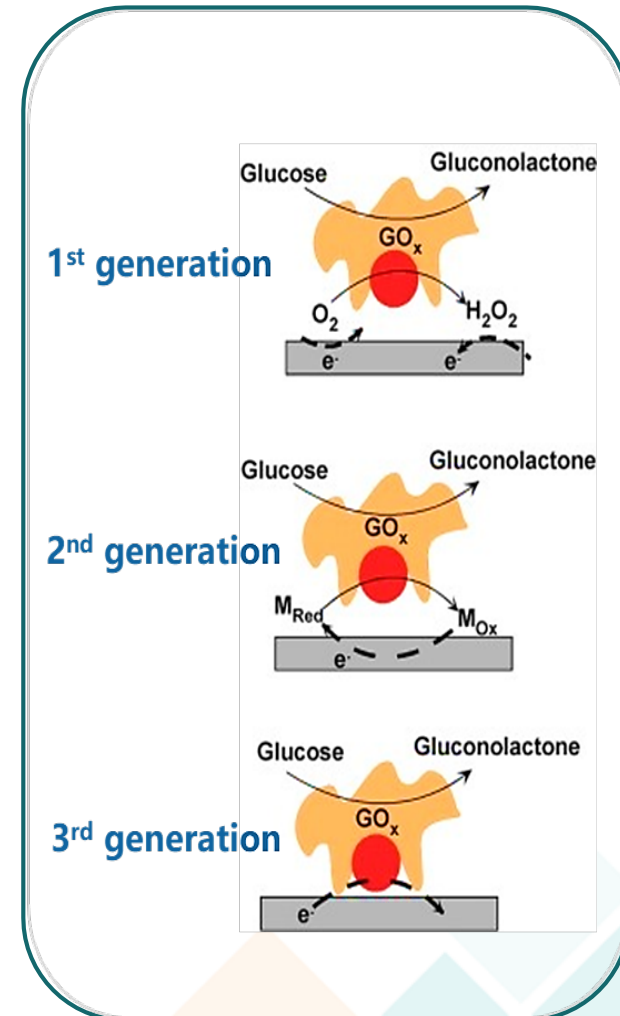
Comparison the families:

Libre vs. Dexcom

Manufacturer	Abbott			Dexcom	
Model	FreeStyle Libre 1	FreeStyle Libre 2	FreeStyle Libre 3	G6	G7
User age	≥4 years old	≥4 years old	≥4 years old	≥2 years old	≥2 years old
Monitoring Time	14 days	14 days	14 days	10 days	10 days
Monitoring Site	back of upper arm	back of upper arm	back of upper arm	abdomen /back of upper arm	abdomen /back of upper arm
MARD Value	11.4%	9.3%	7.9%	9%	8.2%
Test Range	2.2-27.8 mmol/L	2.2-27.8 mmol/L	2.2-27.8 mmol/L	2.2-22.2 mmol/L	2.2-22.2 mmol/L
Output Frequency	15 minutes	1 minutes	1 minutes	5 minutes	5 minutes
Transfer Method	NFC scanning	NFC scanning	real-time Bluetooth	real-time Bluetooth	real-time Bluetooth
Service Life of launcher	one use cycle	one use cycle	one use cycle	Reuse for 3 months	one use cycle
Fingertip Blood Calibration	no calibration	no calibration	no calibration	no calibration	no calibration
Warm-up Time	60 minutes	60 minutes	60 minutes	120 minutes	30 minutes
Data Receiving Device	phone APP/scanner	phone APP/scanner	phone APP	phone APP	phone APP
Interferences	Vitamin C (> 500 mg/day)	Vitamin C (> 500 mg/day)	Vitamin C (> 500 mg/day)	Hydroxyurea, Hydroxycarbamide, Acetaminophen (>1g/6 hours)	Hydroxyurea, Hydroxycarbamide, Acetaminophen (>1g/6 hours)

Sensor Technology Classification of CGM

	1 st Generation	2 nd Generation	3 rd Generation
Reaction	O ₂ / H ₂ O ₂ oxidoreduction	Mediated oxidoreduction	Direct electron transfer
Substrate	O ₂	Oxidized mediators	No
Product	H ₂ O ₂	Reduced mediators	No
Redox potential	500 to 700 mV	50mV	-50mV to 100mV
Enzyme	GOx	GOx	GDH
Interferant	Acetaminophen, O ₂	Ascorbic Acid, O ₂	No
Electrode	Au, Pt or other precious metals	Carbon	Carbon
Advantages	1. mainstream technology 2. mature development 3. easy engineering	1. solve the lack of oxygen in the interstitial liquid 2. reduce the cost of sensor	1. solve the problem of oxygen deficiency in the 1st generation of sensors 2. higher selectivity 3. improved anti-interference ability 4. lower cost
Limitations	1.oxygen deficiency and strong oxidation of hydrogen peroxide 2. sensitivity and accuracy are limited to a certain extent	1. artificial electron acceptors are mostly water-soluble and easy to lose 2. the degree of engineering is difficult	the spatial structure and activity of the enzyme may be affected
CGM manufacturer	Dexcom, Medtronic	Abbott	Sinocare

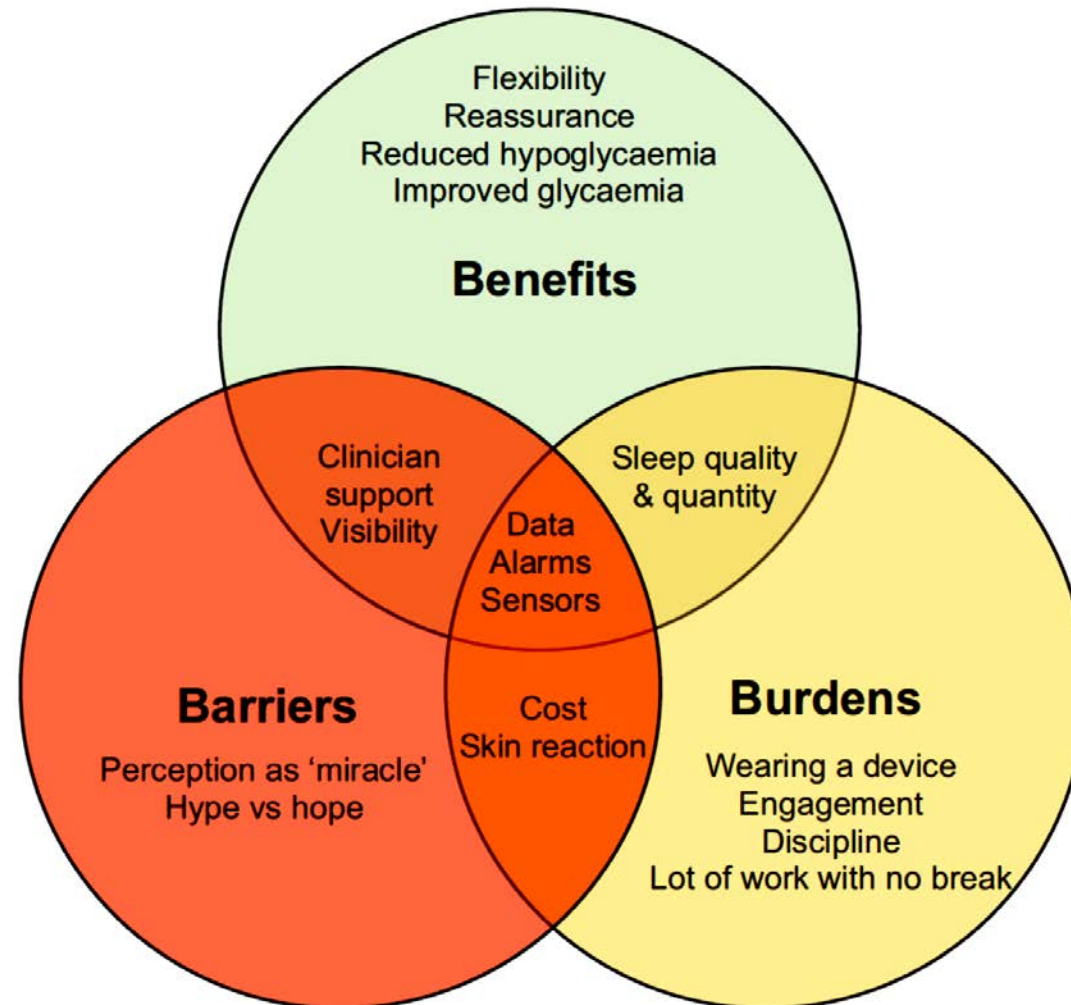


Barriers in using Technology in T₁DM

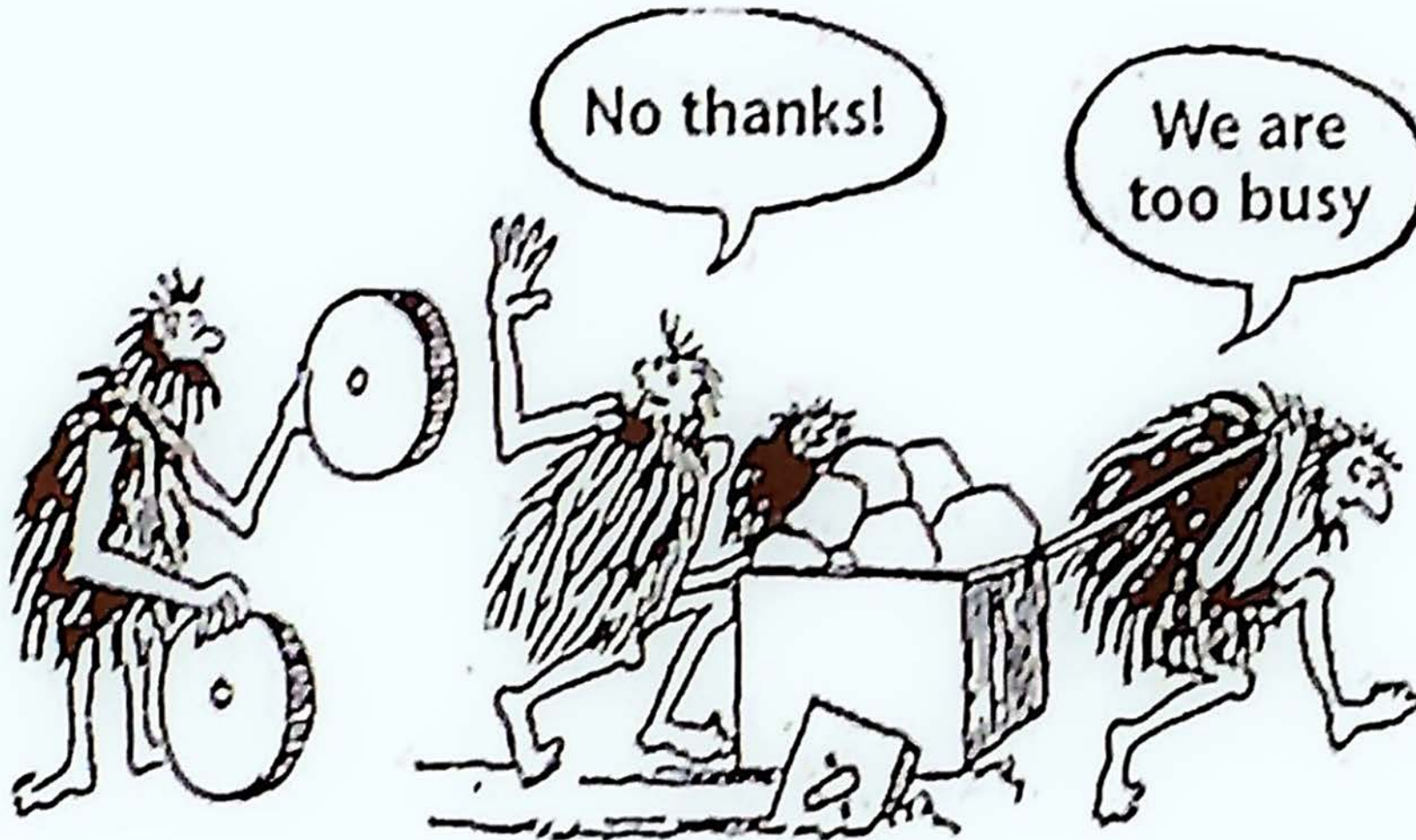
Barriers

- **Cost**
- **Availability**
 - **Sanction**
- **Lack of knowledge**
 - **Public**
 - **HCPs**
- **Sophisticated regulations**
- **Cybersecurity**
- **Too many alarms**
- **Concerns about accuracy**
- **Interference with sports/activities**

The 3Bs associated with using diabetes technologies from the perspective of the PWD-T₁



Any innovation has its' pace of acceptance!



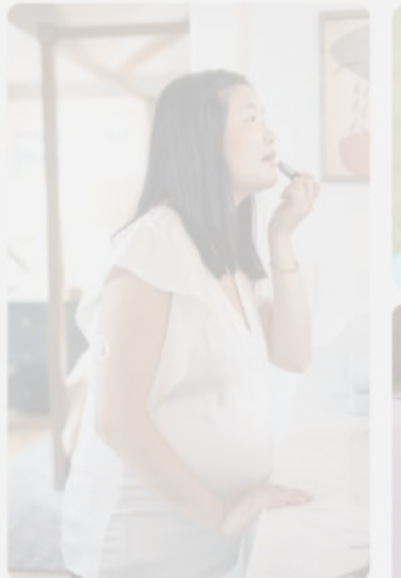
Empowering people to take control of *health*

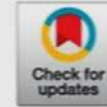
Where We Are

- Type 1
- Type 2 IIT
- Type 2 Basal-Only
- Type 2 Problematic Hypo (Non-Insulin)

Where We Are Going

- Type 2 Non-Insulin
- Pre-Diabetes
- Gestational Diabetes
- Patient Monitoring
- Health & Wellness





Maturation of CGM and Glycemic
Measurements Beyond HbA_{1c}—
A Turning Point in Research
and Clinical Decisions

Matthew C. Riddle,¹
Hertzel C. Gerstein,² and
William T. Cefalu³

Diabetes Care 2017;40:1611–1613 | <https://doi.org/10.2337/dci17-0049>

“Periodically, a new idea, method, or tool leads to a turning point in the management of diabetes. We believe such a moment is now upon us, brought by development of reliable devices for continuous glucose monitoring.”



Thank you

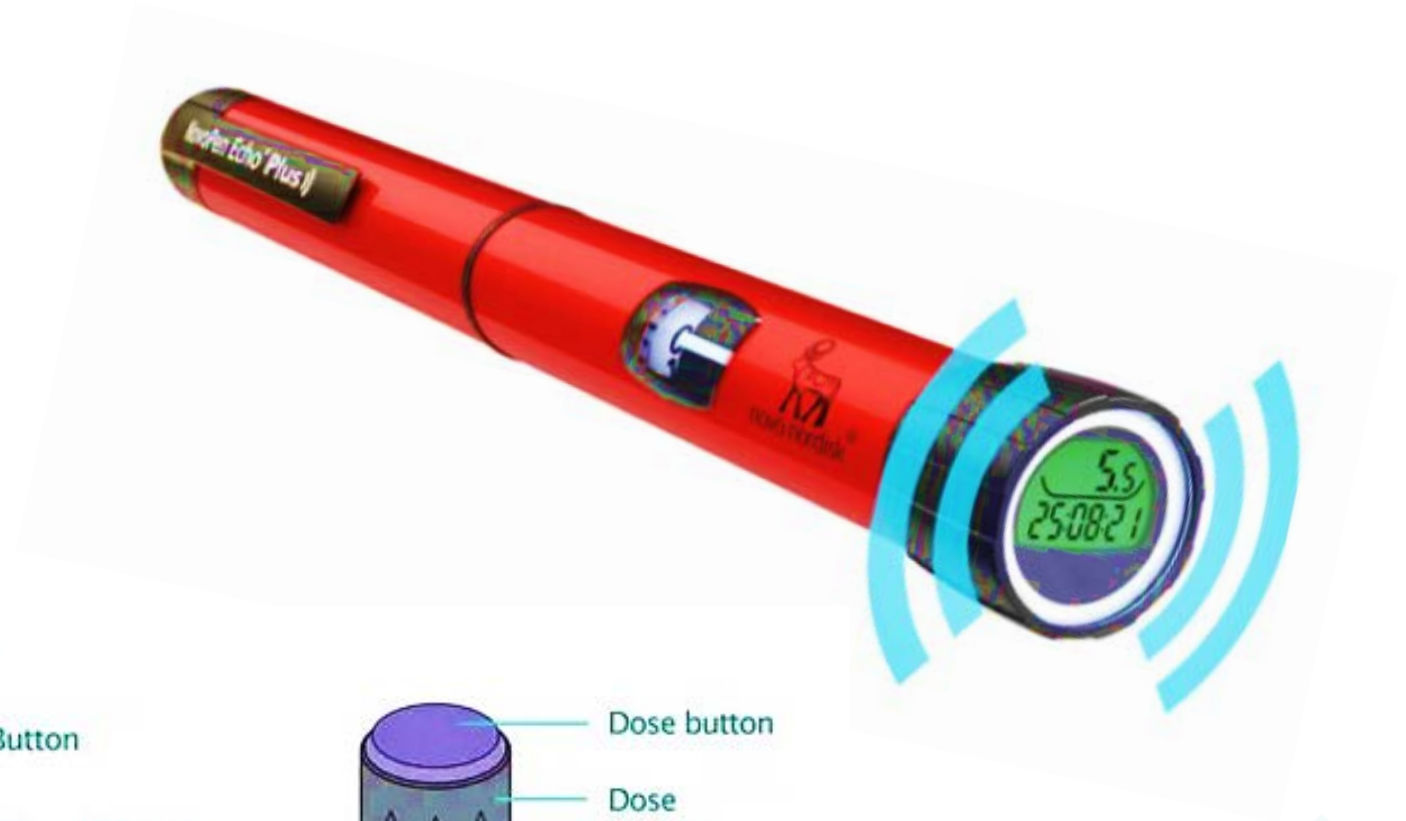
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Connectivity in diabetes

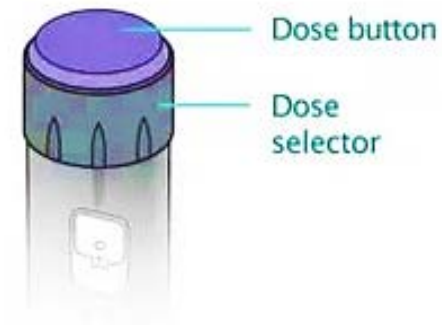
You will not forget



Conhecendo o SoloSmart e a caneta






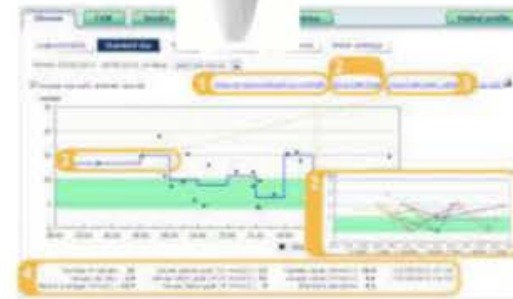
SoloSmart



Sanofi SoloStar[®]
insulin pen

Connectivity Solutions

Smart insulin caps	SoloSmart Button	Tempo Smart Button	Dialog
Picture			
Firm	Sanofi	Lilly	Novo Nordisk
Fits on	Solostar	Tempopen	FlexTouch
Approval	CE-label	CE- an FDA-label verwacht eind 2022	?
Dedicated app	yes: Mallya app	yes	no
Sends data to	Gluci-Check & RDCP, YourLoops?	MySugr, RDCP, Glooko, MyDiabby, Welldoc, Dexcom	MySugr, Glooko, Libreview from summer 2022?
Battery	Rechargeable via USB	1 year warranty	?



shutterstock.com - 719478730



Medtronic



SANOFI 

Dexcom Smart Insulin Pens



☆☆☆☆☆

Smart Insulin Pen Dexcom

\$69.88



☆☆☆☆☆

Smart Insulin Pen Dexcom

\$69.88



☆☆☆☆☆

Smart Insulin Pen Dexcom

\$69.88

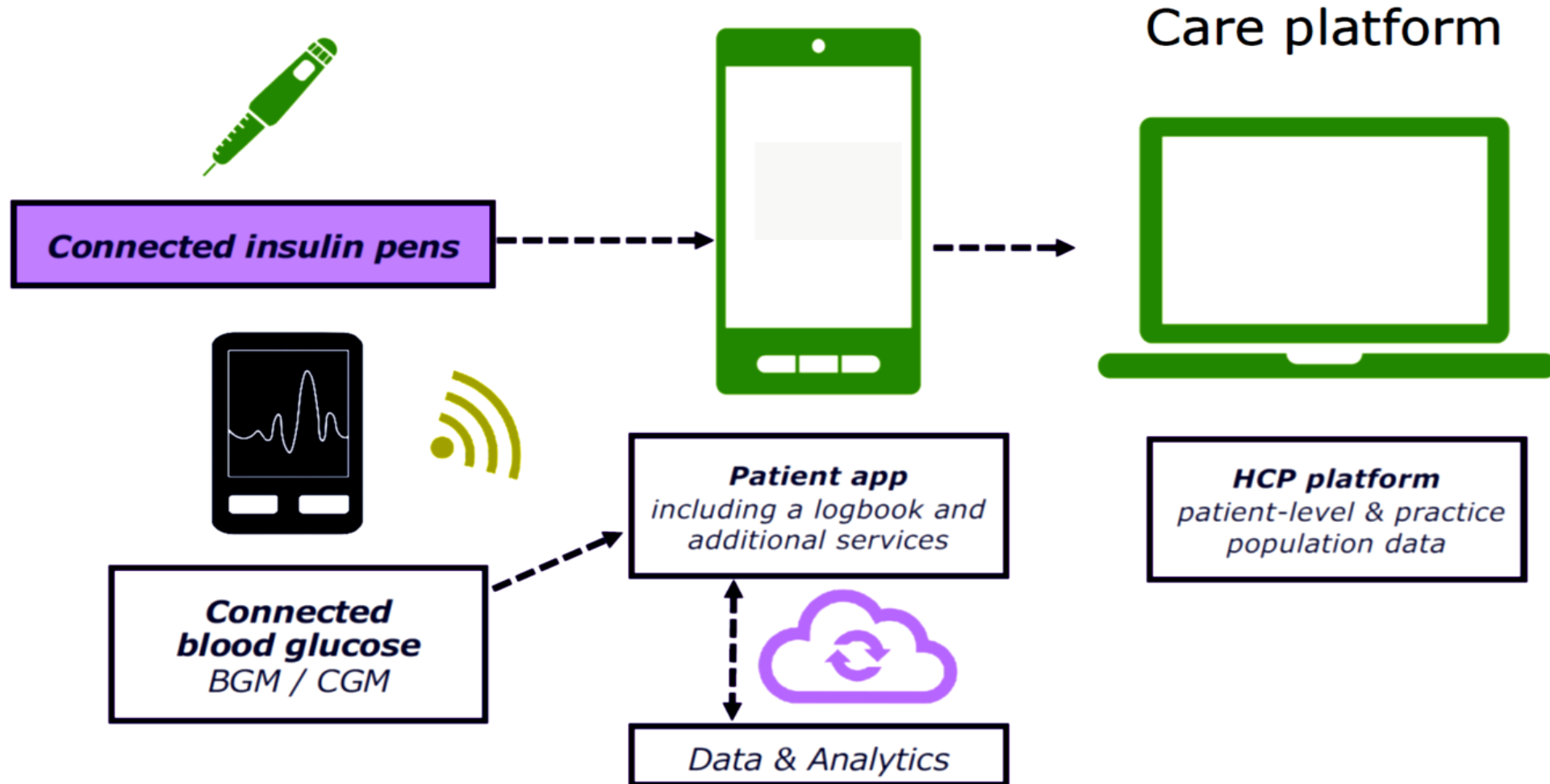


☆☆☆☆☆

Smart Insulin Pen Dexcom

\$69.88

Connected Pens and meters are enablers for data driven consultations → and possibly decision support systems



It becomes the user's choice

- To drive themselves, or to be driven

MDI + Sensor



Closed loops -
automated insulin
delivery



What about Iranian efforts?

Insightfully Scanned Glucose Monitoring (iSGM) Novel Modality in Diabetes Monitoring

FREE SENS
SMART View

Insights beyond the numerical glucose results

SMBG Data Quality

Provides insights on SMBG Adherence

Point in Range

Provides insights on glycemic variability

Modal View

Provides insights intra-day variability

Hypo Risk Analysis

Provides insights on hypoglycemic events



Abstract Number: 995

Abstract Title:

Insightfully Scanned Glucose Monitoring (iSGM) In Clinical Decision Making And Patient-physician Communication: A Novel Modality For Resource-limited Settings

Background and Aims

CGM is becoming standard of care in diabetes, however not easily accessible in low- and middle-income countries (LMICs). Capillary blood glucose monitoring is the most accessible tool. Patient-reported Blood Glucose (BG) data are known to be inaccurate. Physician's access to aggregated BG data is limited with complexity of Bluetooth and cable-connected devices. Insightfully scanned glucose monitoring (iSGM), a novel integration of NFC enabled glucose meter with a mobile application can provide physicians with glucose analysis including point-of-care (PIR), modal view and hypoglycemia report. This study evaluates the benefits of iSGM in therapeutic decision making and patient-physician communication.

Methods

Individuals with T1DM and T2DM were consecutively recruited from seventeen practices. Patient-reported BGs were compared to iSGM reports. Physician's perspective was evaluated using a questionnaire.

Results

161 Individuals, 53% female, 52% T2DM, median age 38 years (IQR 15-59), median diabetes duration 8 years (IQR 4-15) and median HbA1c 8% (IQR 7.05-9.50) completed the study. 9282 glucose values were downloaded. 31.7% were missing in patient-reported data. 29.6% of patient-reported values were fabricated. 39% of hypoglycemia events were missing. 55.4% of patient-reported data was clinically reliable. 100% of physicians agreed iSGM provides a comprehensive analysis on glycemic control, while only 17% agreed BG logging was helpful for therapeutic adjustments. 94% of physicians agreed iSGM is an effective tool for hypoglycemia identification, facilitates patient-physician communication and patient-centered diabetes care.

Conclusions

iSGM compared to BG logging is an effective modality for insightful and accurate therapeutic adjustments and may facilitates diabetes care especially in LMICs.

